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(12) **United States Patent**
Tsukashima et al.

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(45) **Date of Patent: Sep. 6, 2016**

(54) **PERCUTANEOUS TRANSCATHETER REPAIR OF HEART VALVES**

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(73) Assignee: **Valcare, Inc.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 332 days.

(21) Appl. No.: **13/935,193**

(22) Filed: **Jul. 3, 2013**

(65) **Prior Publication Data**

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Related U.S. Application Data

(62) Division of application No. 13/198,582, filed on Aug. 4, 2011, now Pat. No. 8,518,107.

(60) Provisional application No. 61/492,279, filed on Jun. 1, 2011, provisional application No. 61/383,681, filed on Sep. 16, 2010, provisional application No. 61/370,754, filed on Aug. 4, 2010.

(51) **Int. Cl.**
A61F 2/24 (2006.01)

(52) **U.S. Cl.**
CPC .... ***A61F 2/2466*** (2013.01); ***A61F 2/2448*** (2013.01); *A61F 2/2442* (2013.01); (Continued)

(58) **Field of Classification Search**
None
See application file for complete search history.

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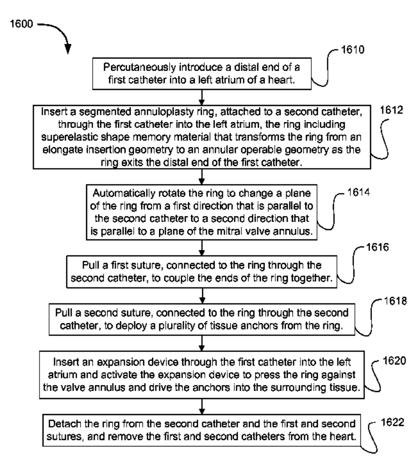
Primary Examiner — Yashita Sharma
Assistant Examiner — Rebecca Preston
(74) *Attorney, Agent, or Firm* — Pepper Hamilton LLP

(57) **ABSTRACT**

Apparatus, systems, and methods are provided for repairing heart valves through percutaneous transcatheter delivery and fixation of annuloplasty rings to heart valves. An annuloplasty ring includes an outer hollow member including a plurality of segments. Adjacent segments cooperate with one another to change the outer hollow member from an elongate insertion geometry to an annular operable geometry. The annuloplasty ring also includes an internal anchor member located at least partially within the outer hollow member. The internal anchor member includes a plurality of anchors configured to attach the annuloplasty ring to tissue of a heart valve annulus. The internal anchor member is configured to move the plurality of anchors with respect to a plurality of windows in the outer hollow member to selectively deploy the plurality of anchors through the respective windows.

5 Claims, 46 Drawing Sheets



(52) **U.S. Cl.**
CPC *A61F 2/2445* (2013.01); *A61F 2210/0014* (2013.01); *A61F 2220/0016* (2013.01); *A61F 2220/0033* (2013.01); *A61F 2220/0075* (2013.01); *A61F 2250/001* (2013.01); *A61F 2250/0004* (2013.01); *A61F 2250/0067* (2013.01); *A61F 2250/0096* (2013.01)

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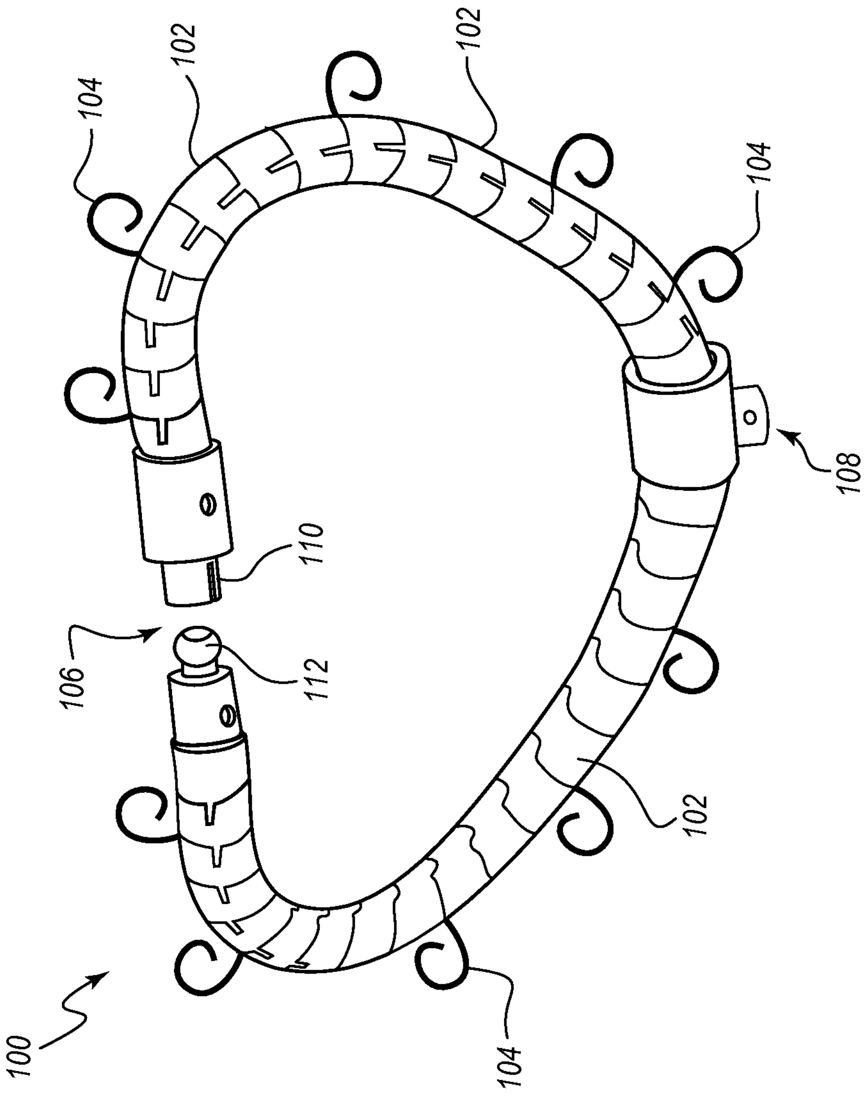


FIG. 1

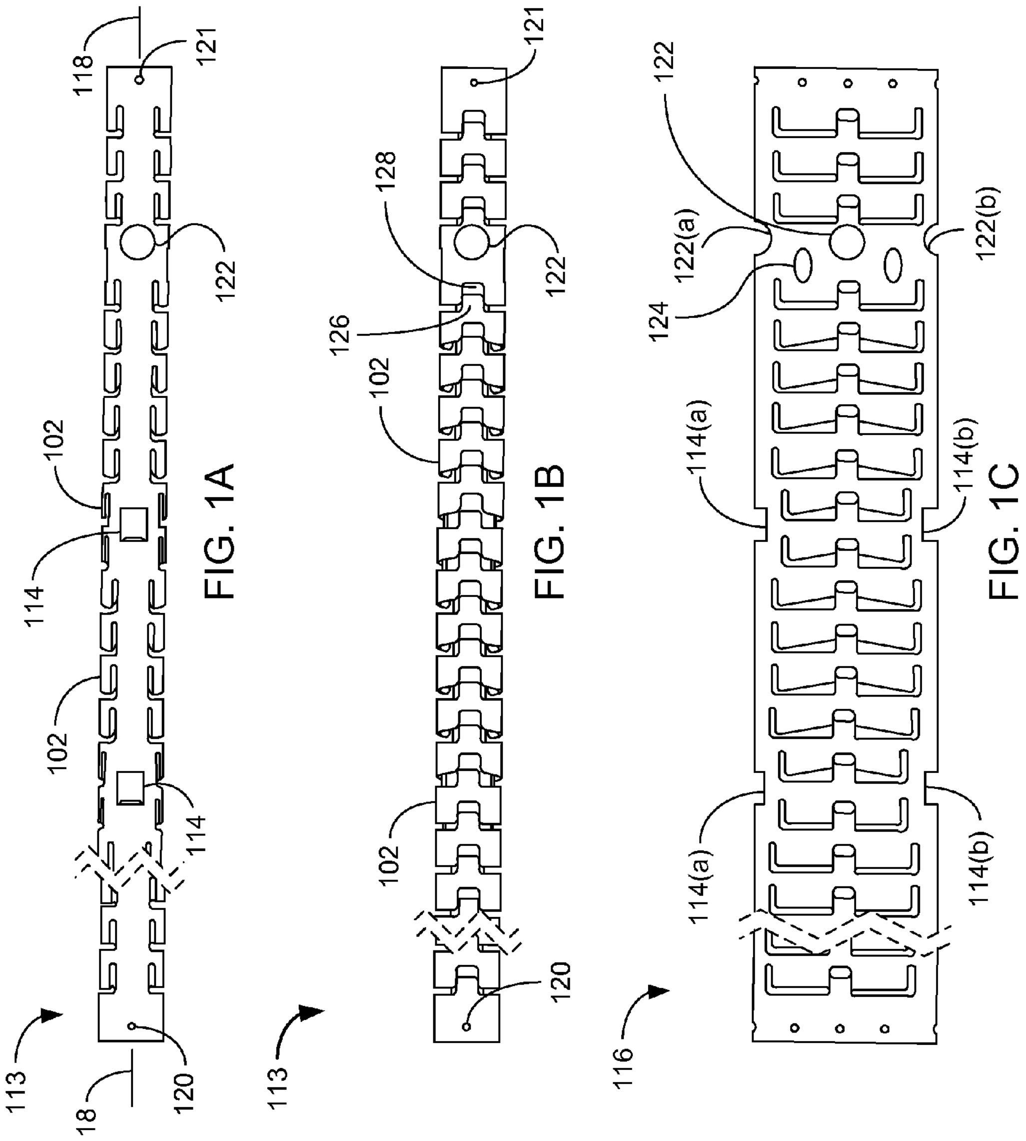


FIG. 1A

FIG. 1B

FIG. 1C

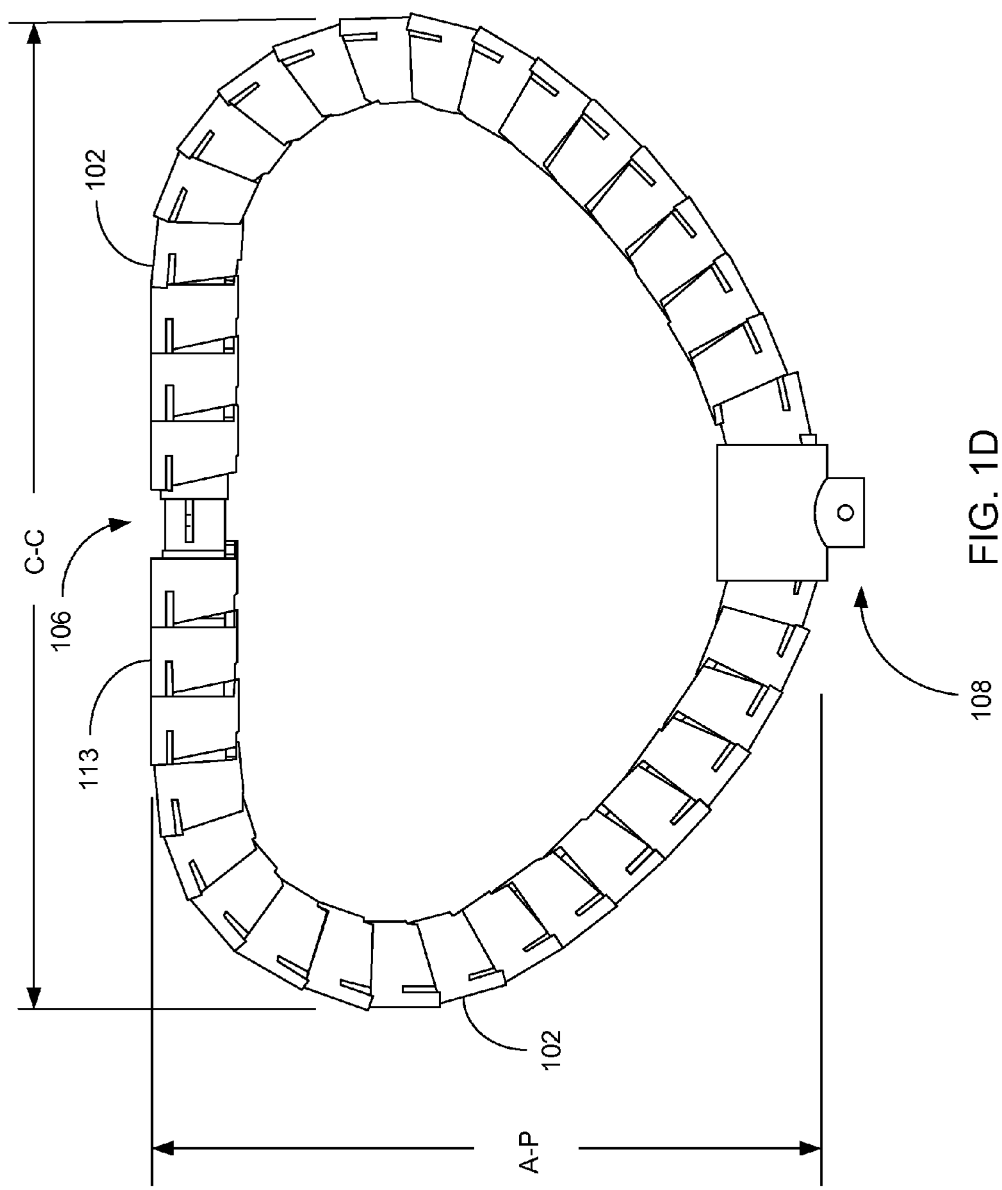


FIG. 1D

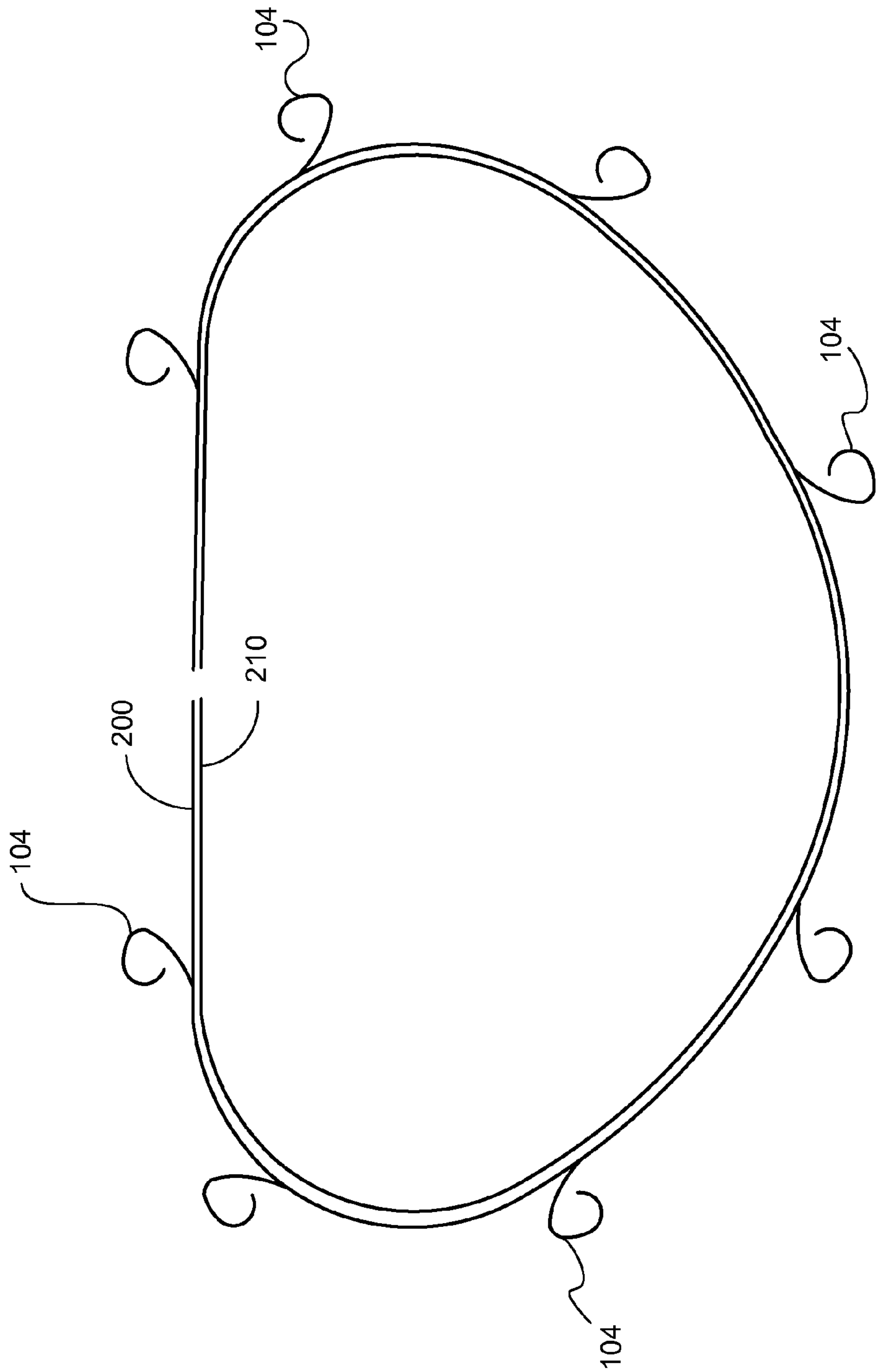


FIG. 2A

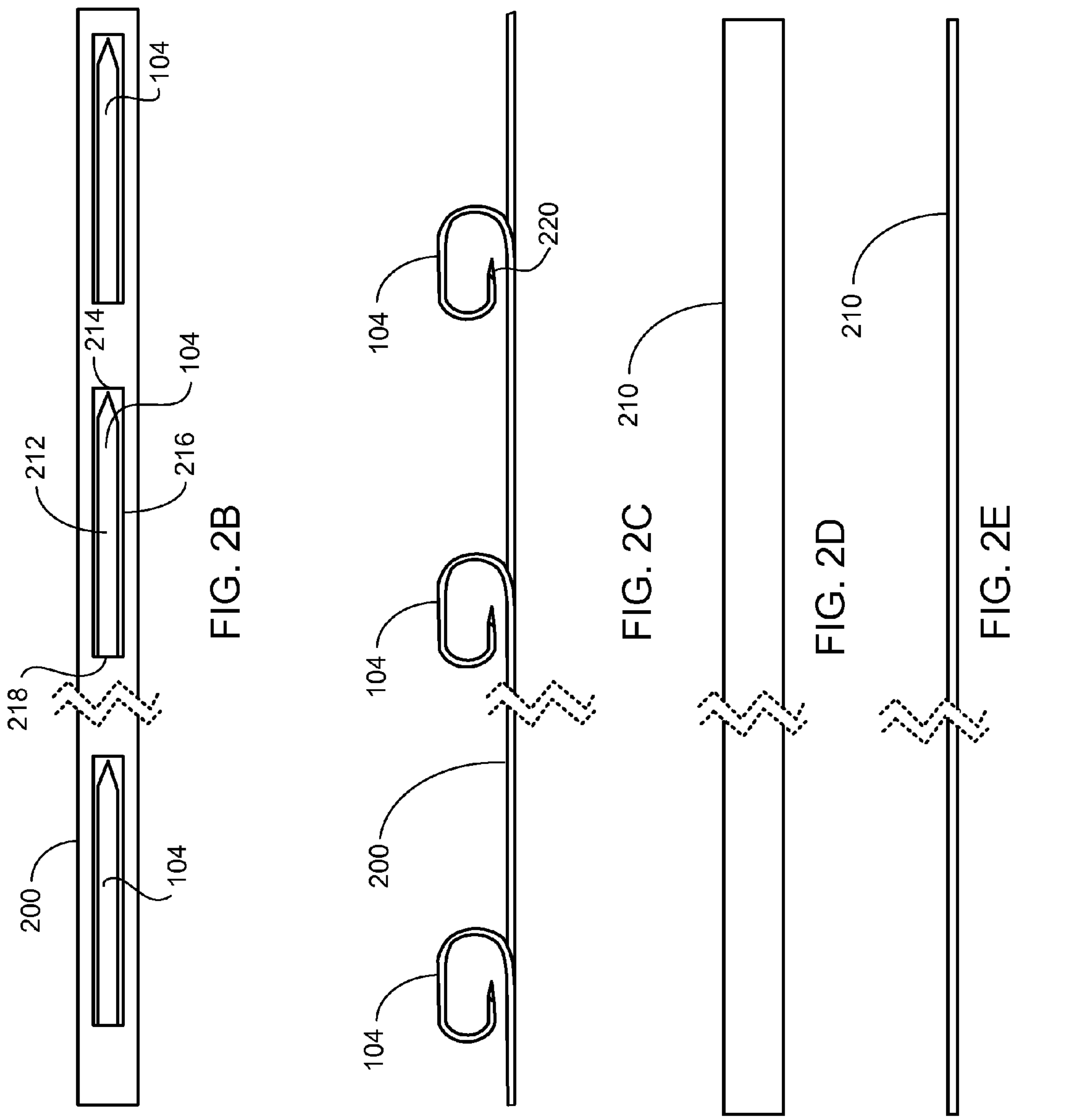
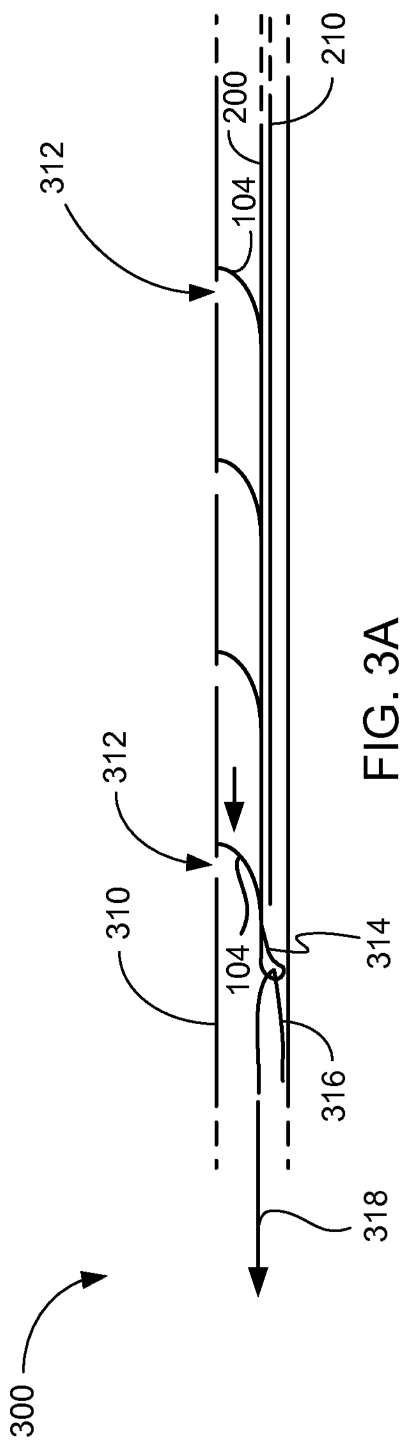


FIG. 2B

FIG. 2C

FIG. 2D

FIG. 2E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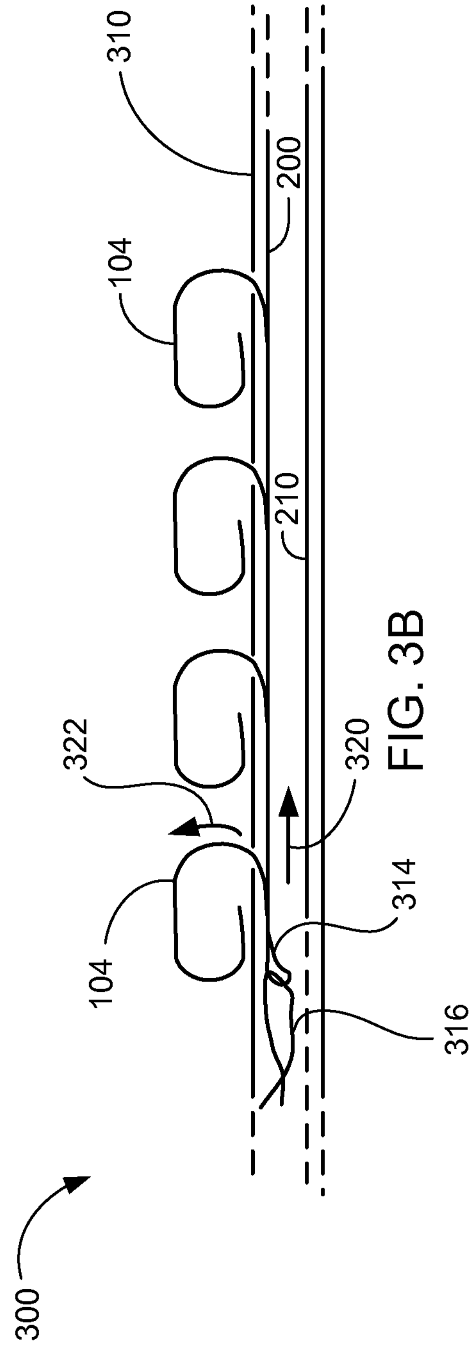
210
104
312
310
104
314
316
318
300

FIG. 3A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300

FIG. 3B

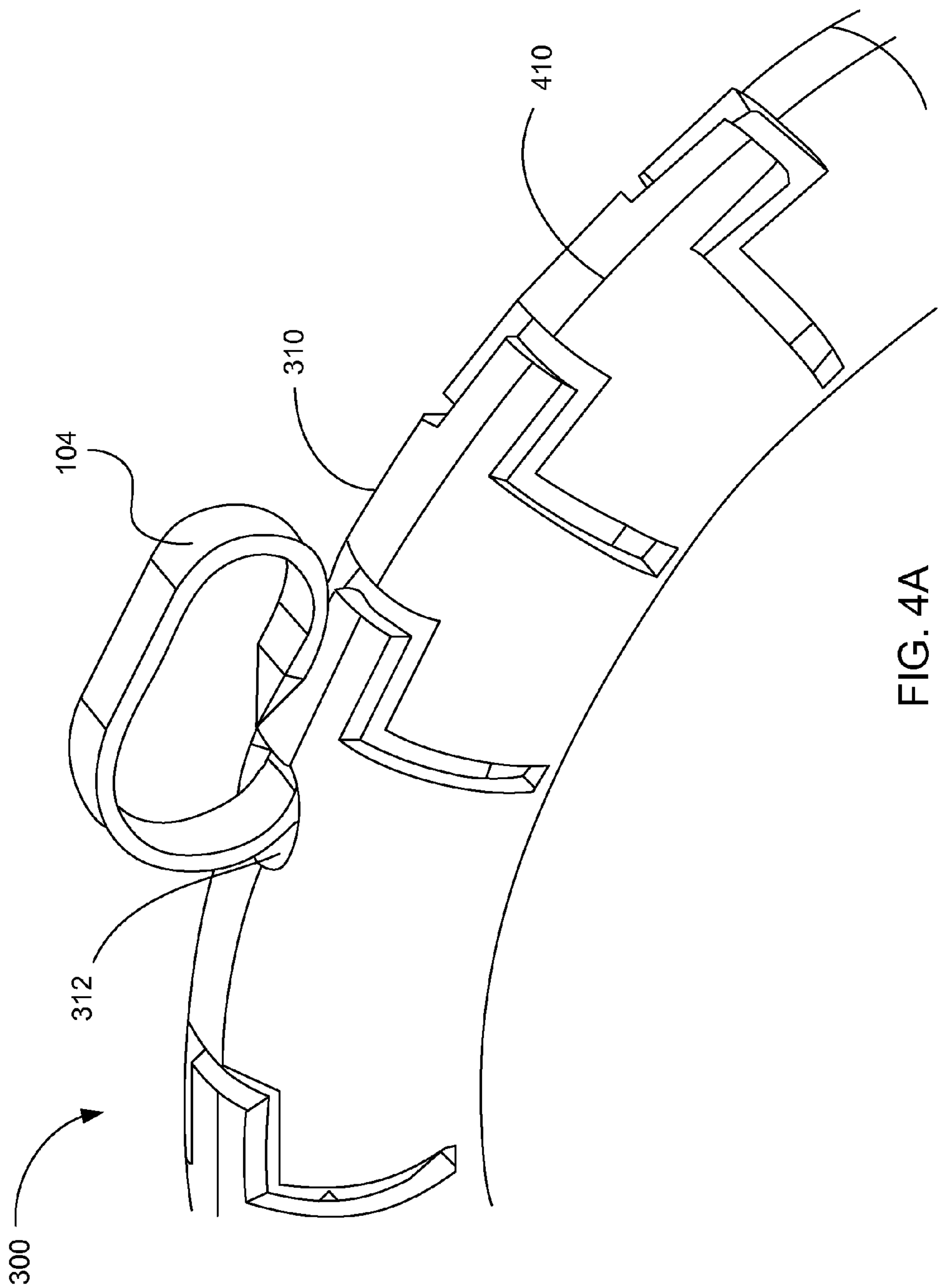


FIG. 4A

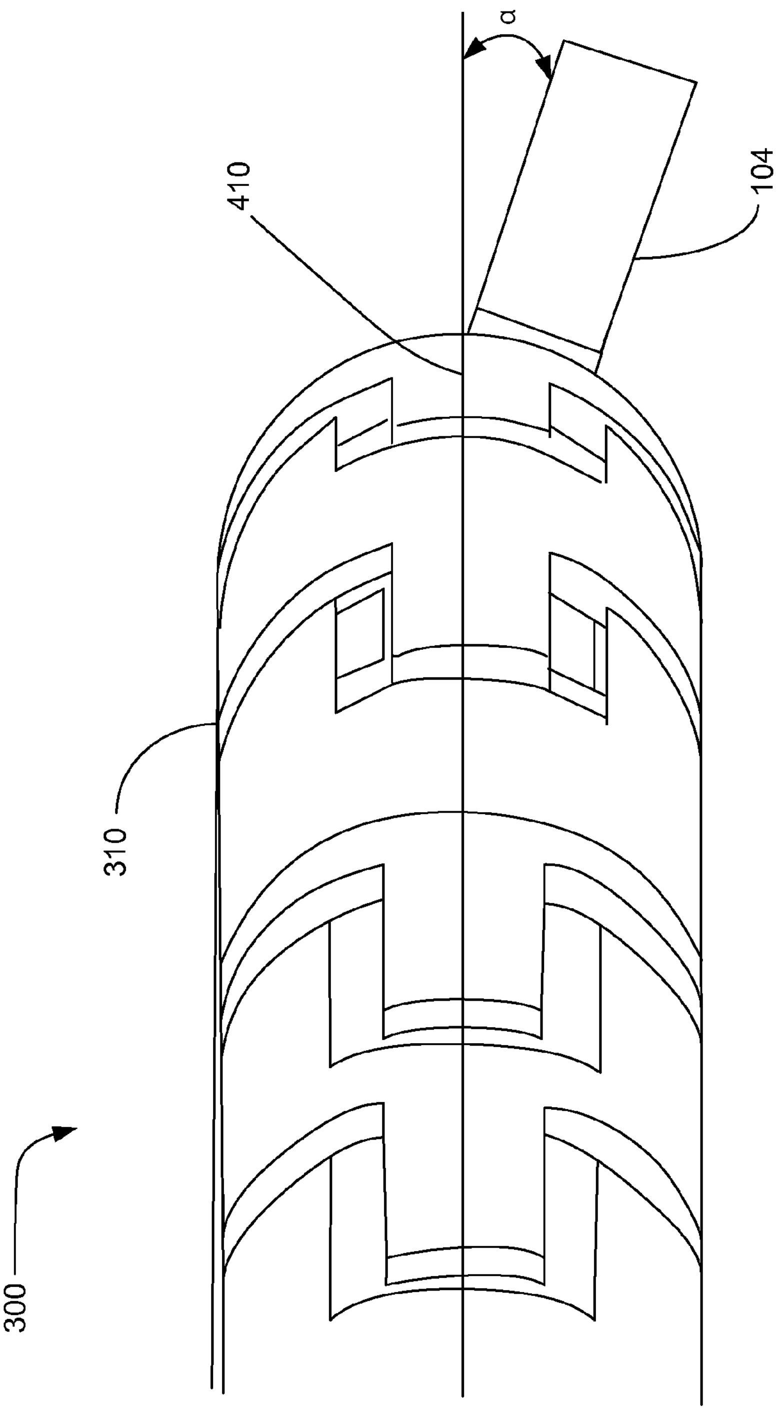


FIG. 4B

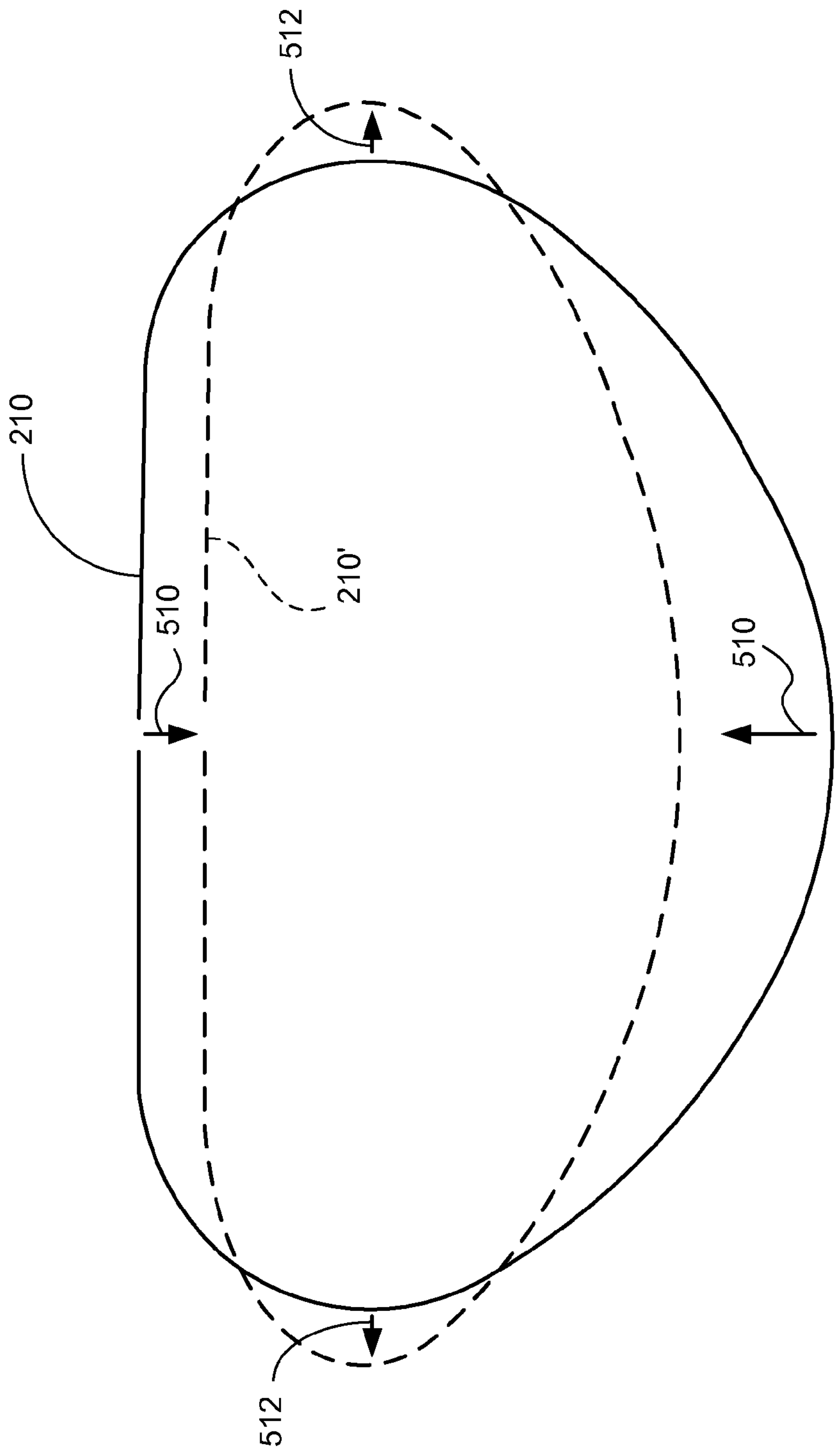
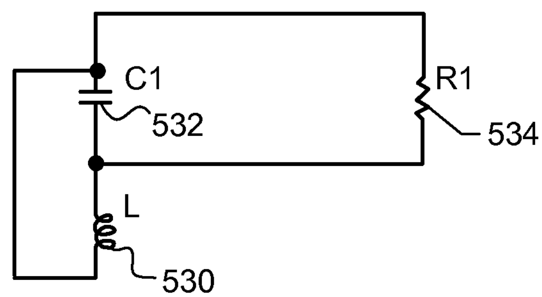
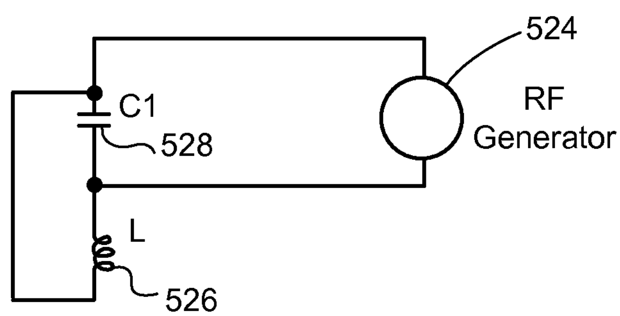


FIG. 5



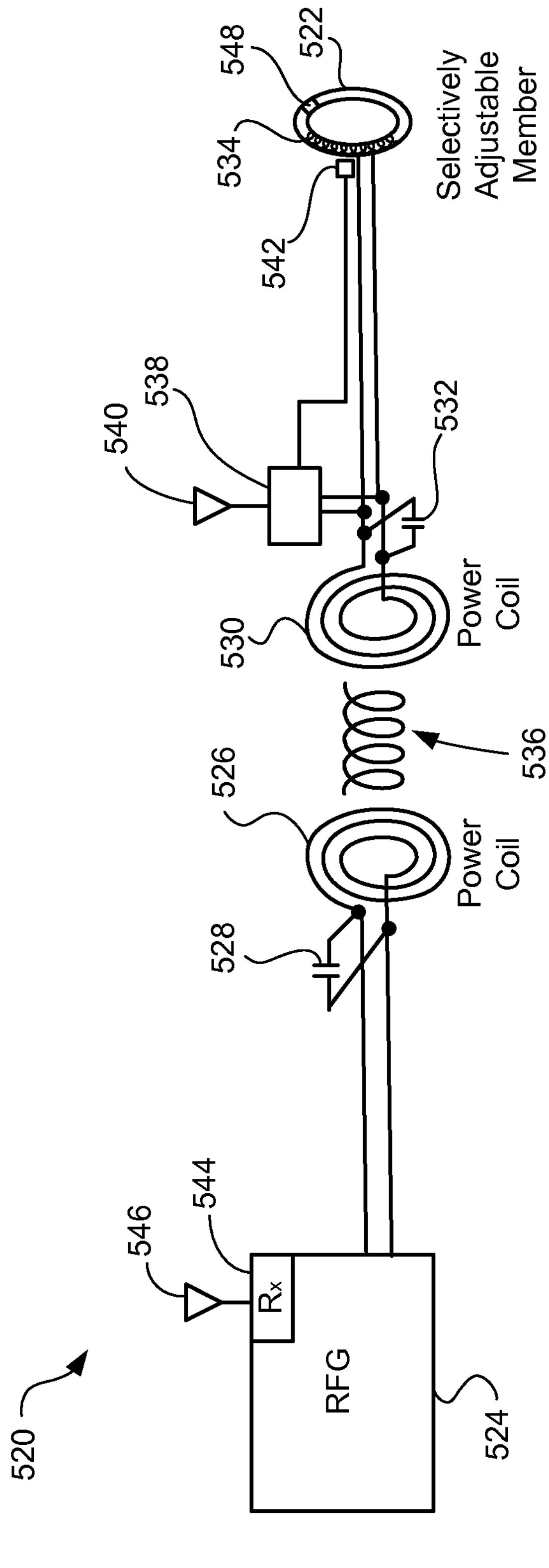
Circuitry in Ring

FIG. 5A



RF Power Source Circuitry

FIG. 5B



520
RFG
Rx
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Power Coil
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530
Power Coil
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522
Selectively Adjustable Member

FIG. 5C

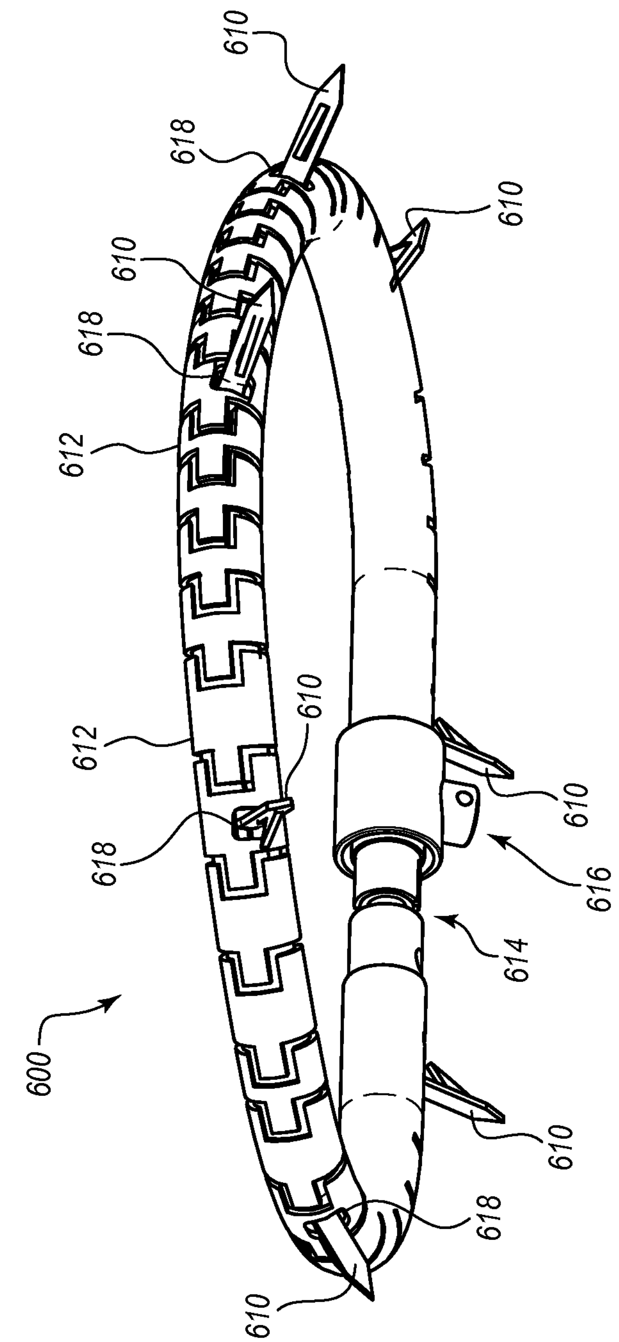

FIG. 6A

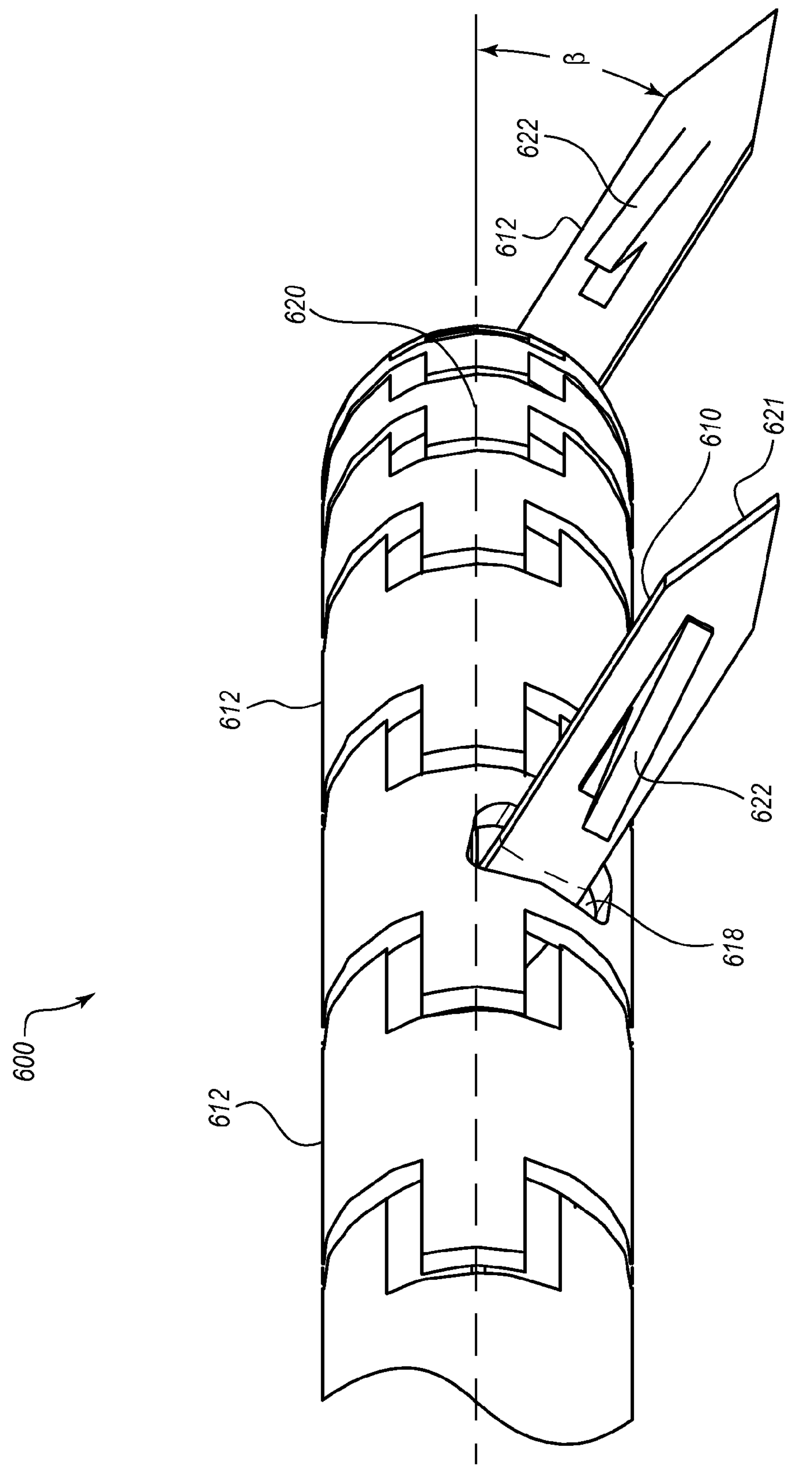

FIG. 6B

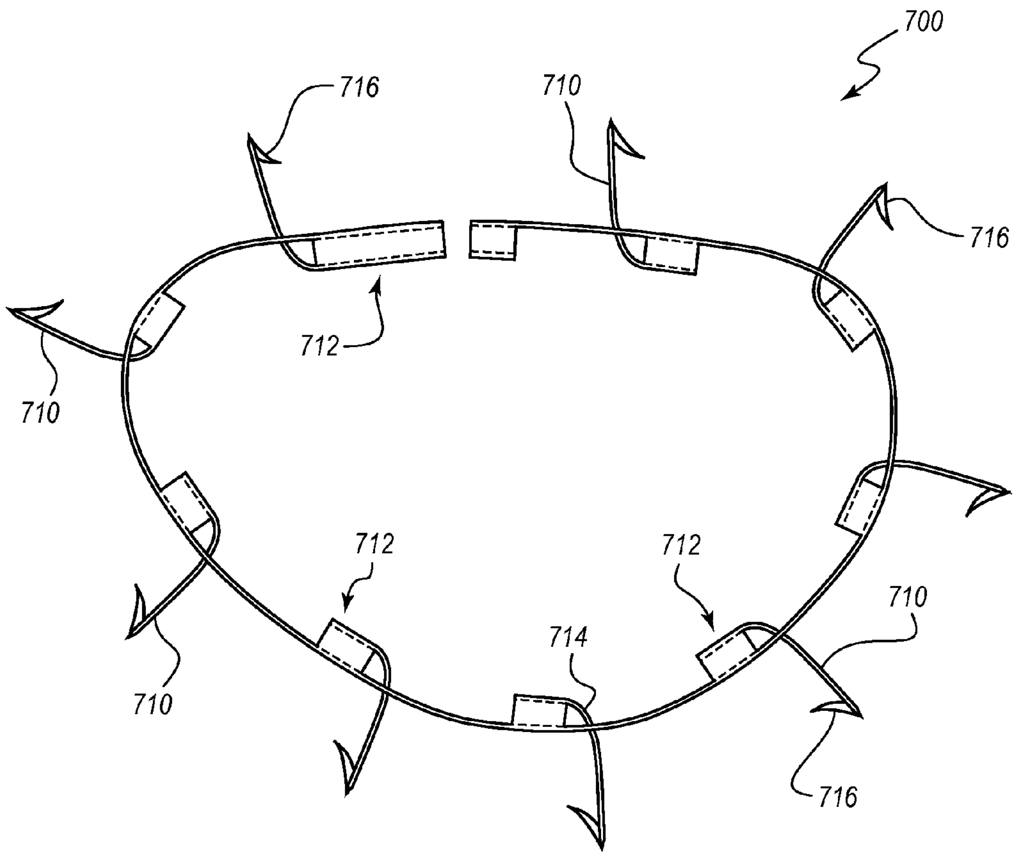

FIG. 7

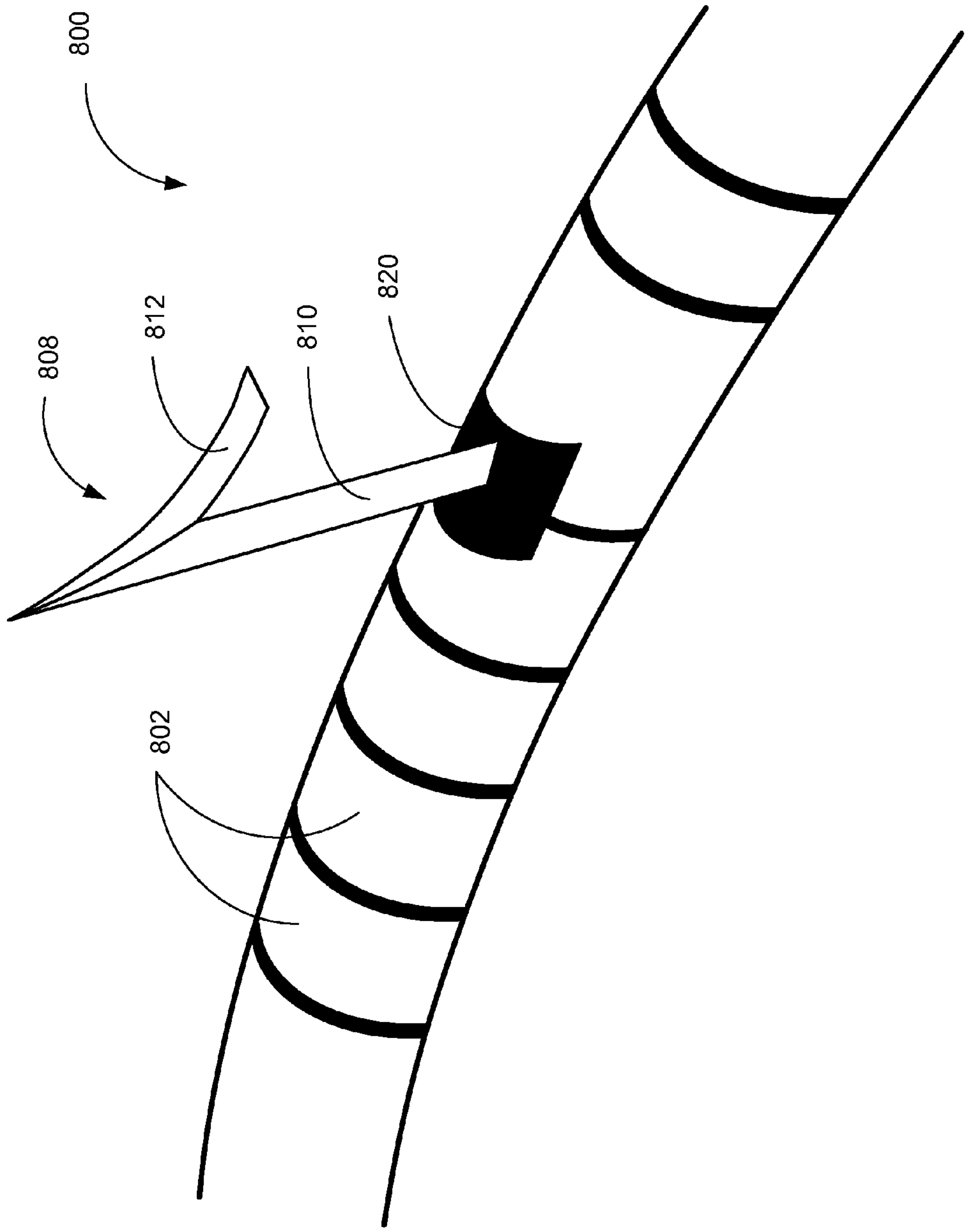

FIG. 8A

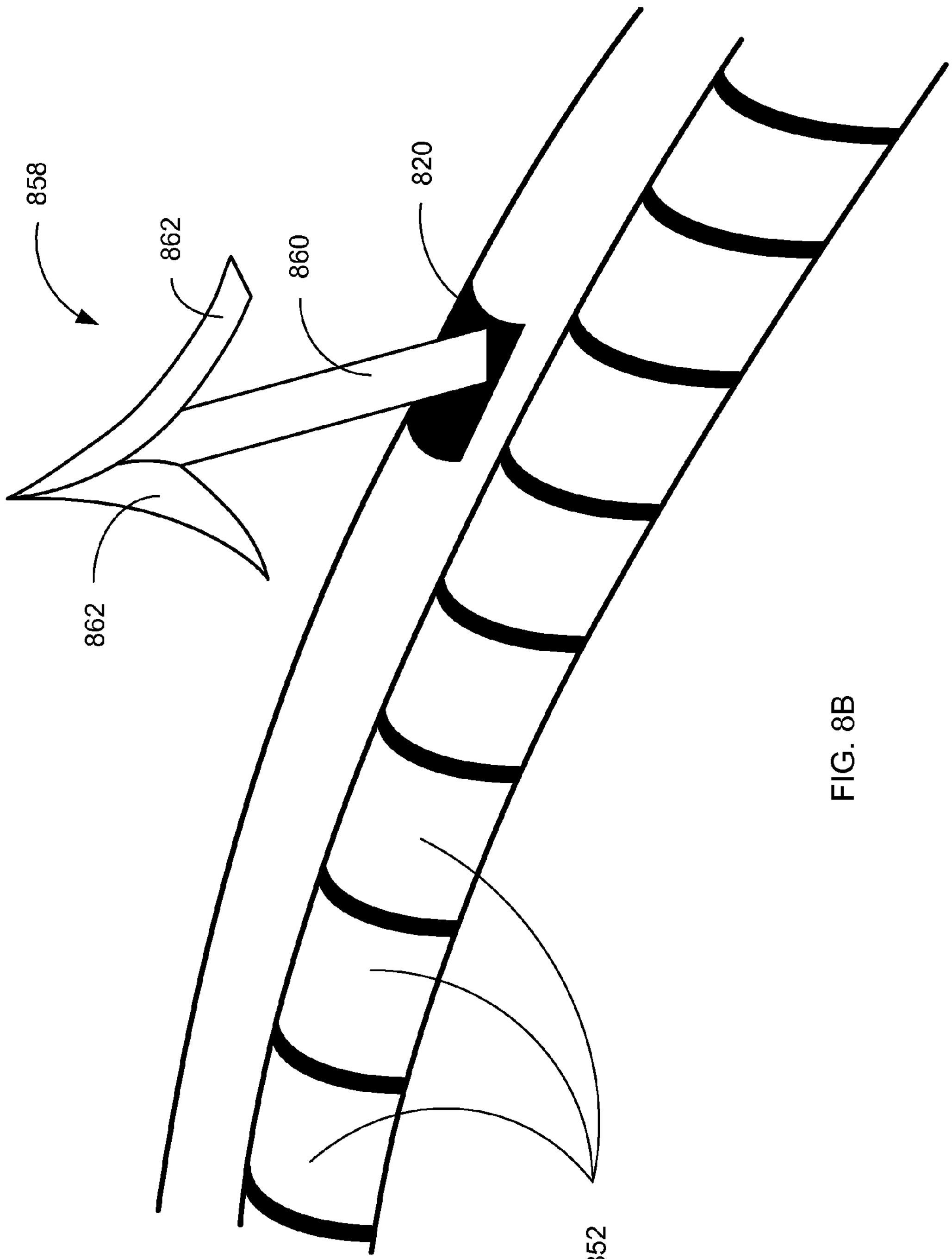

FIG. 8B

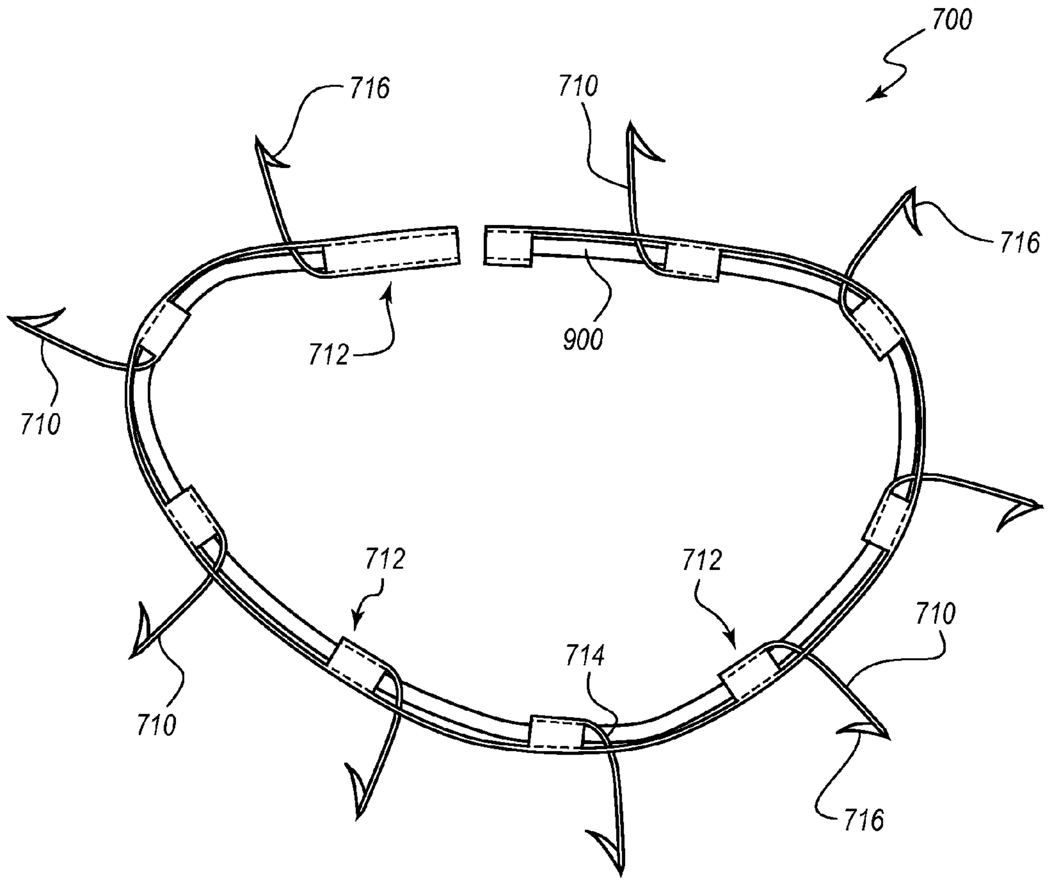

FIG. 9

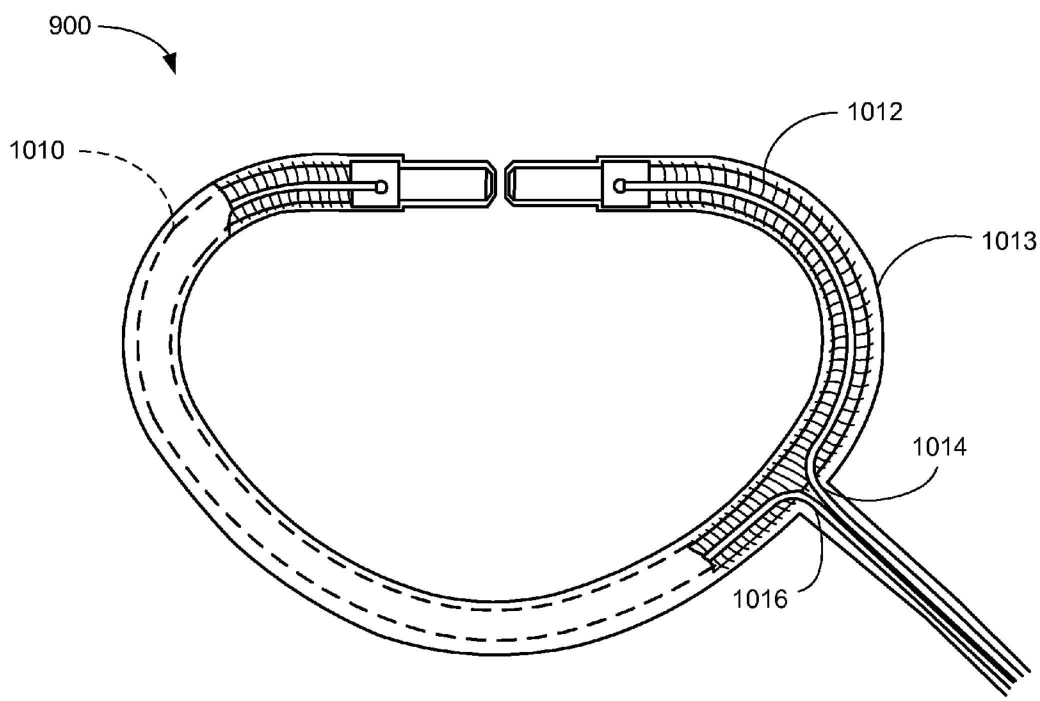

FIG. 10

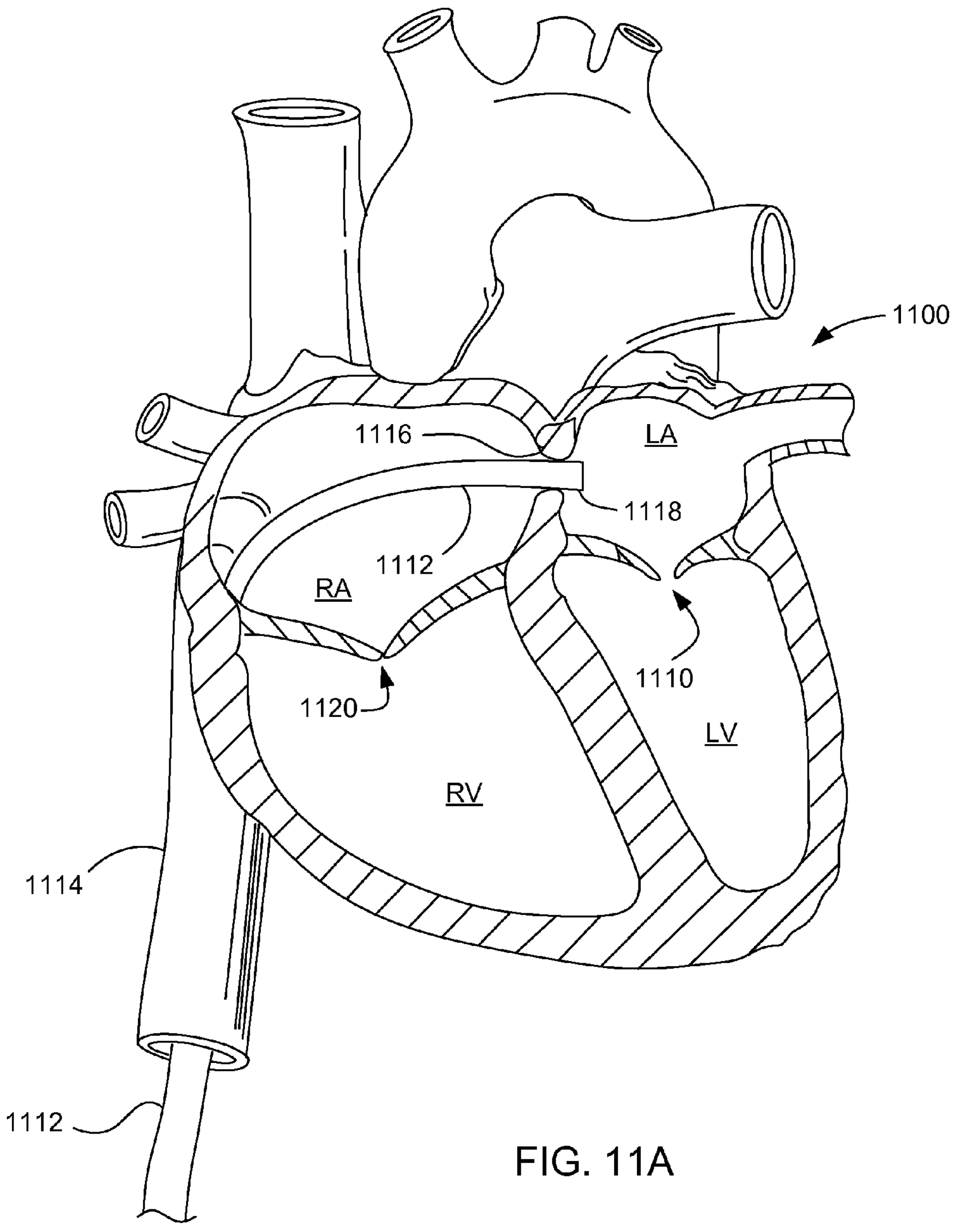

FIG. 11A

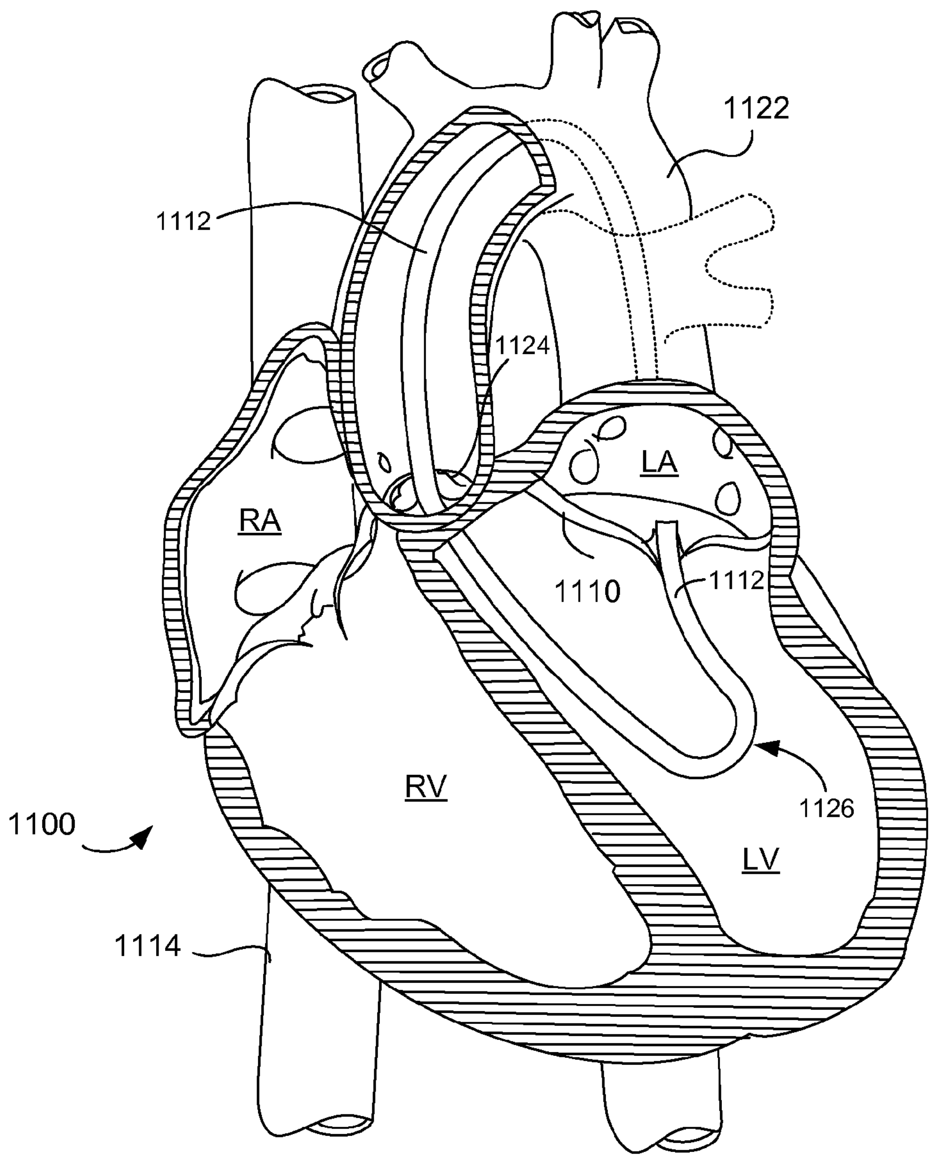

FIG. 11B

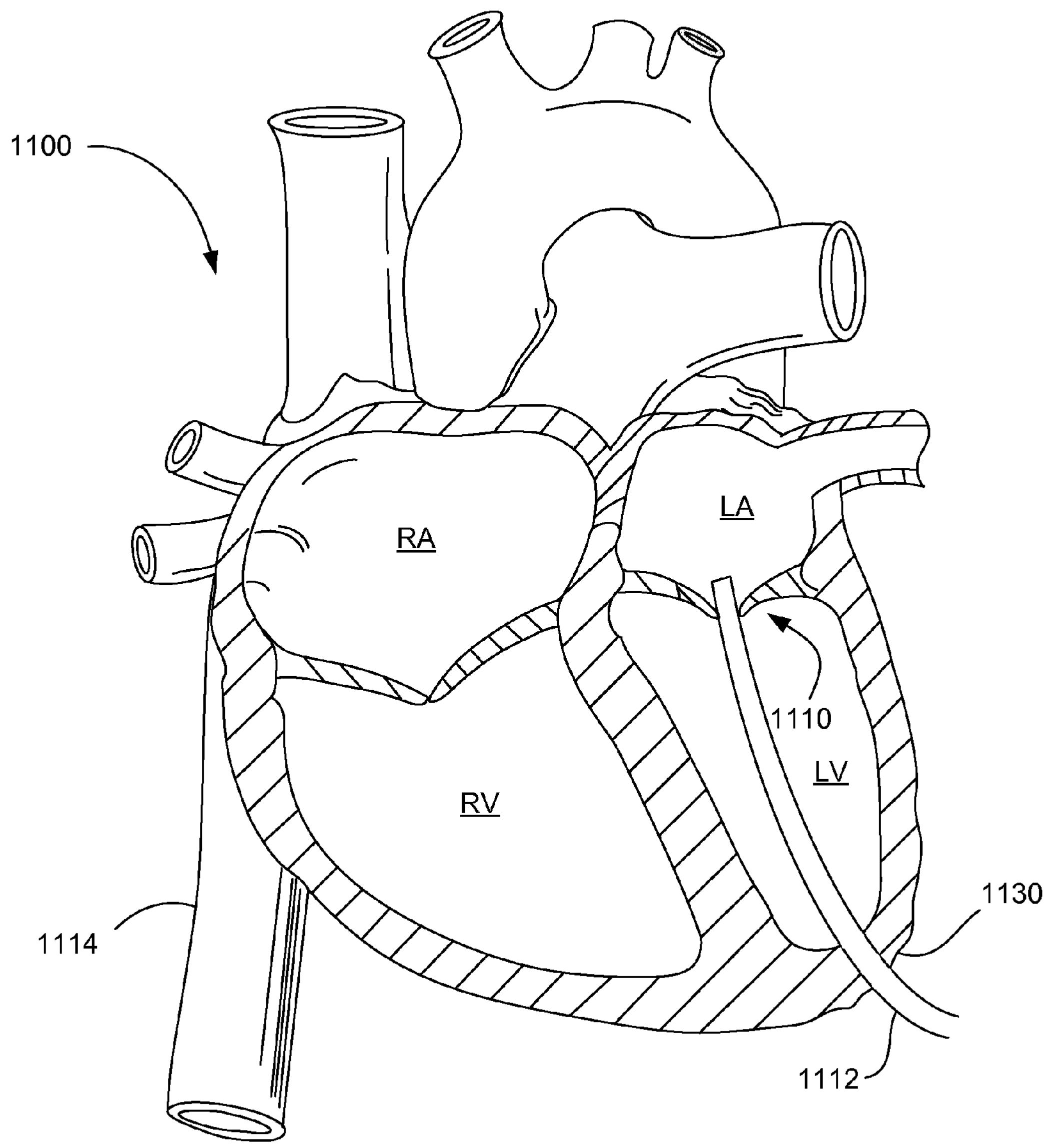

FIG. 11C

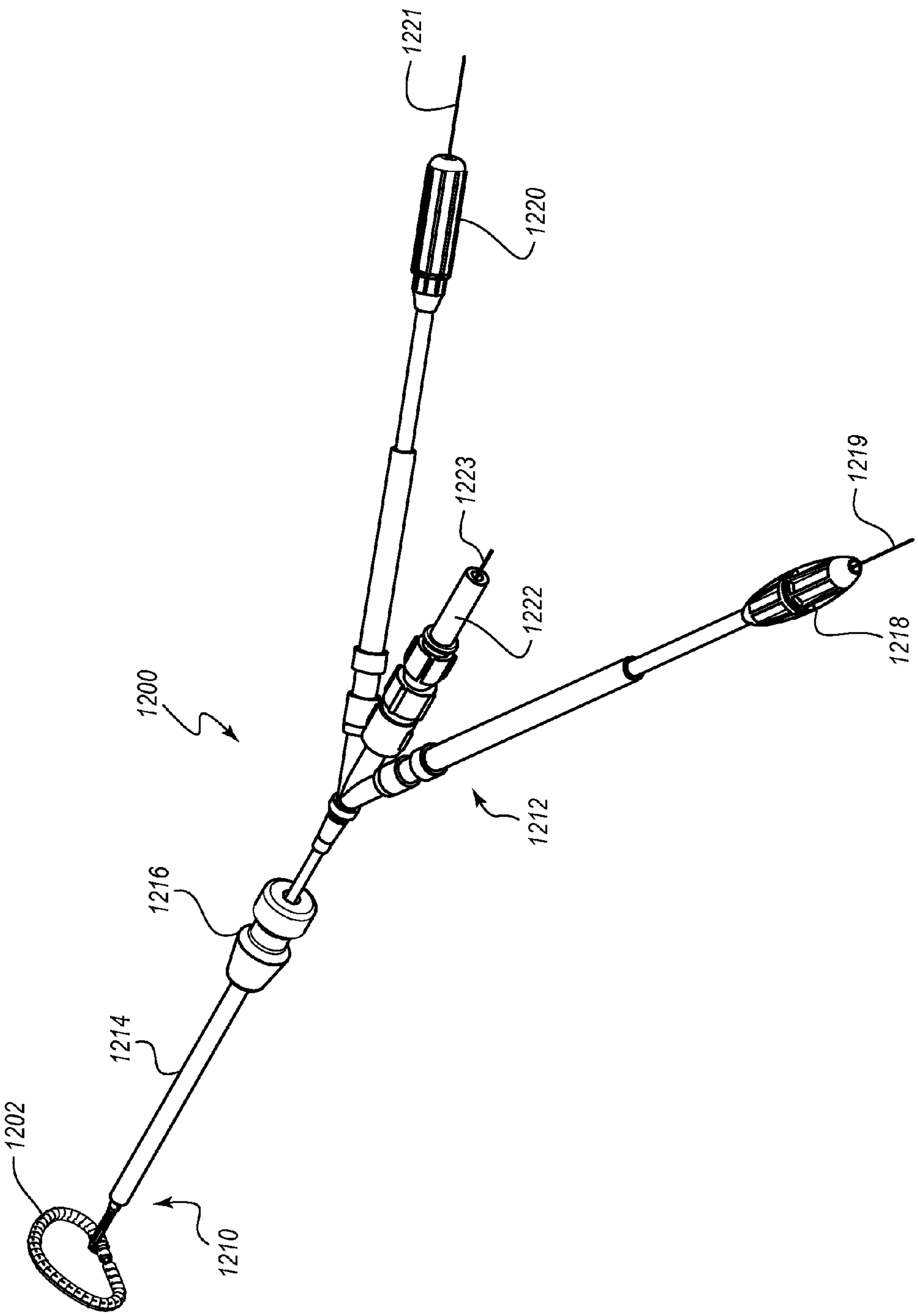

FIG. 12A

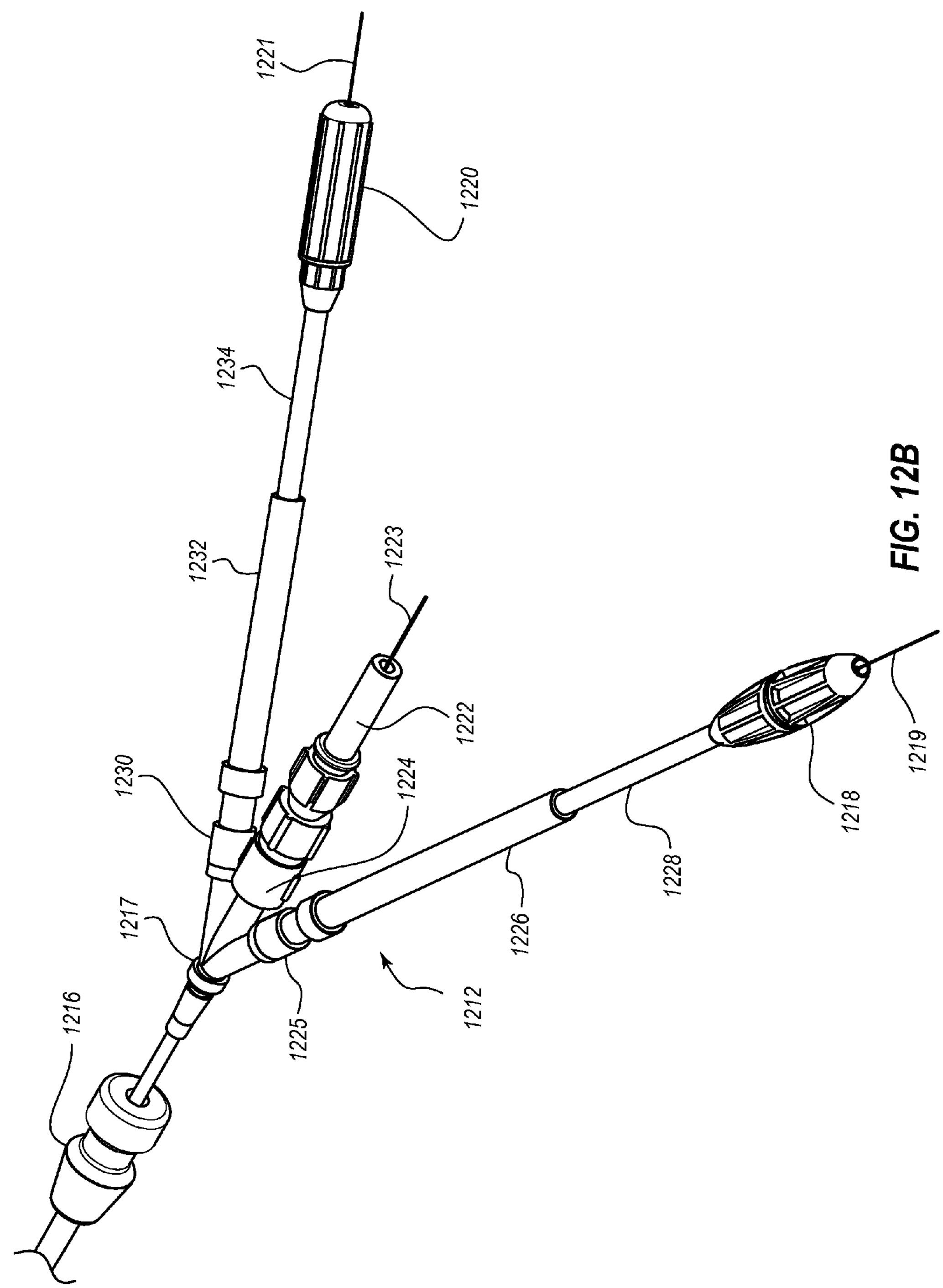
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FIG. 12B

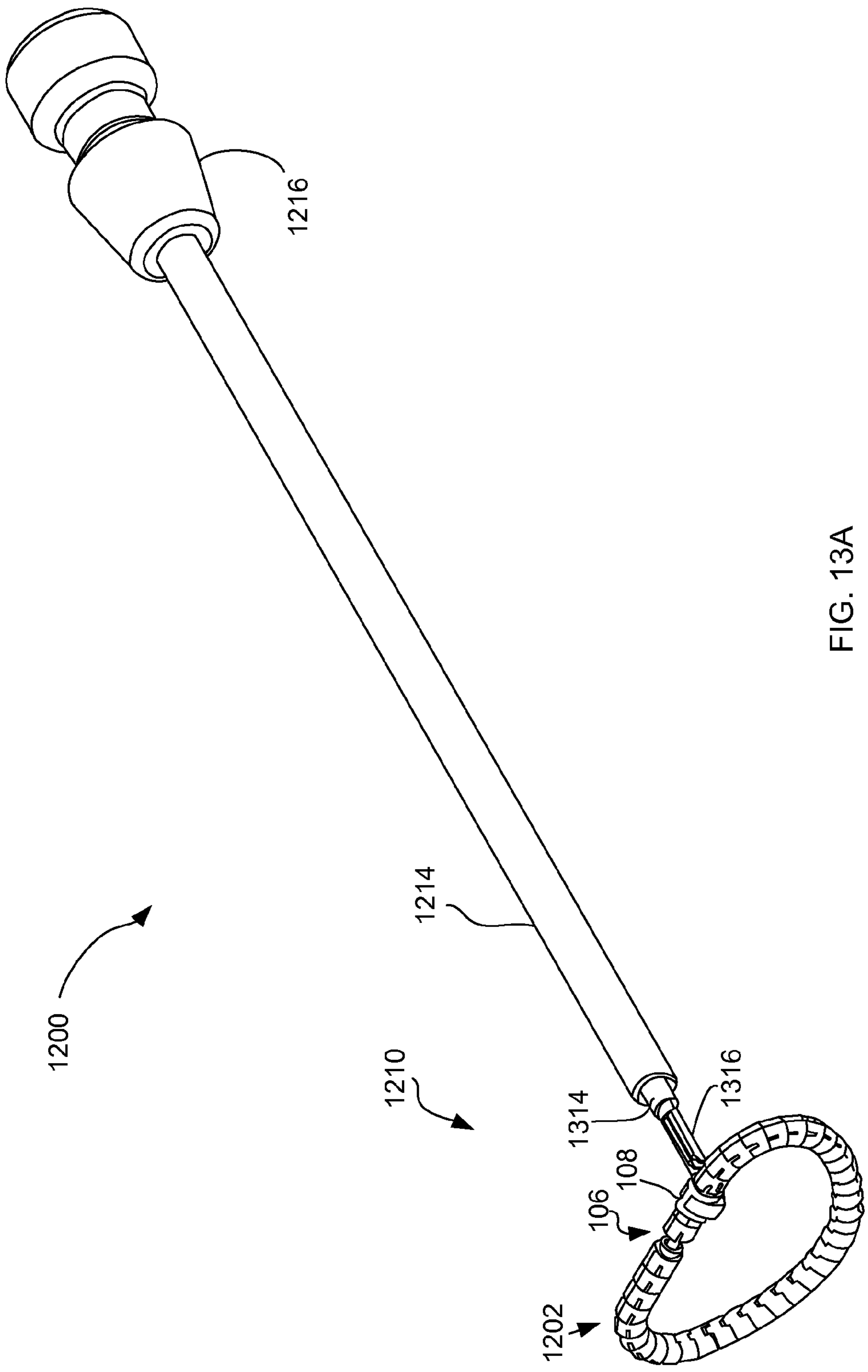

FIG. 13A

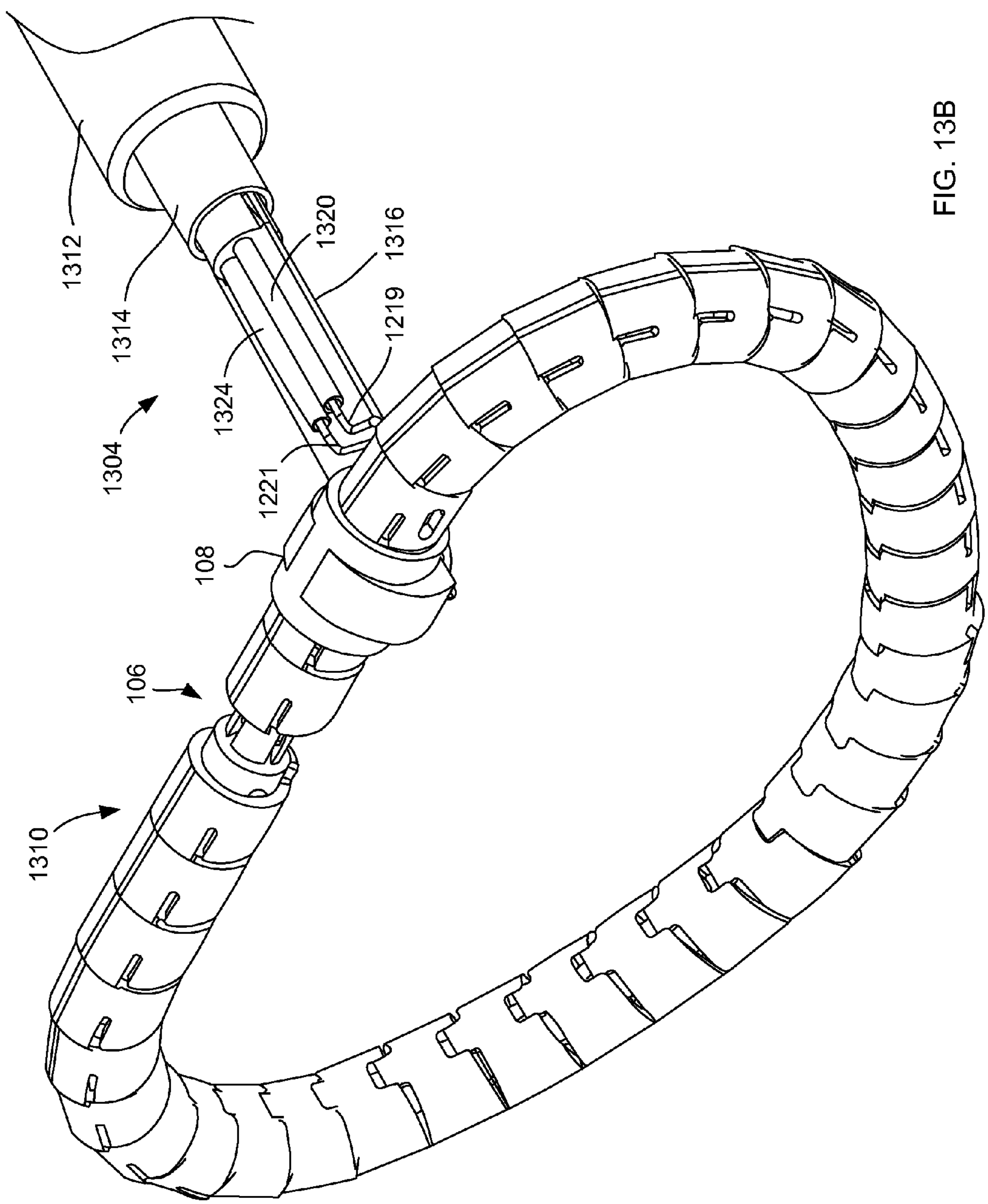

FIG. 13B

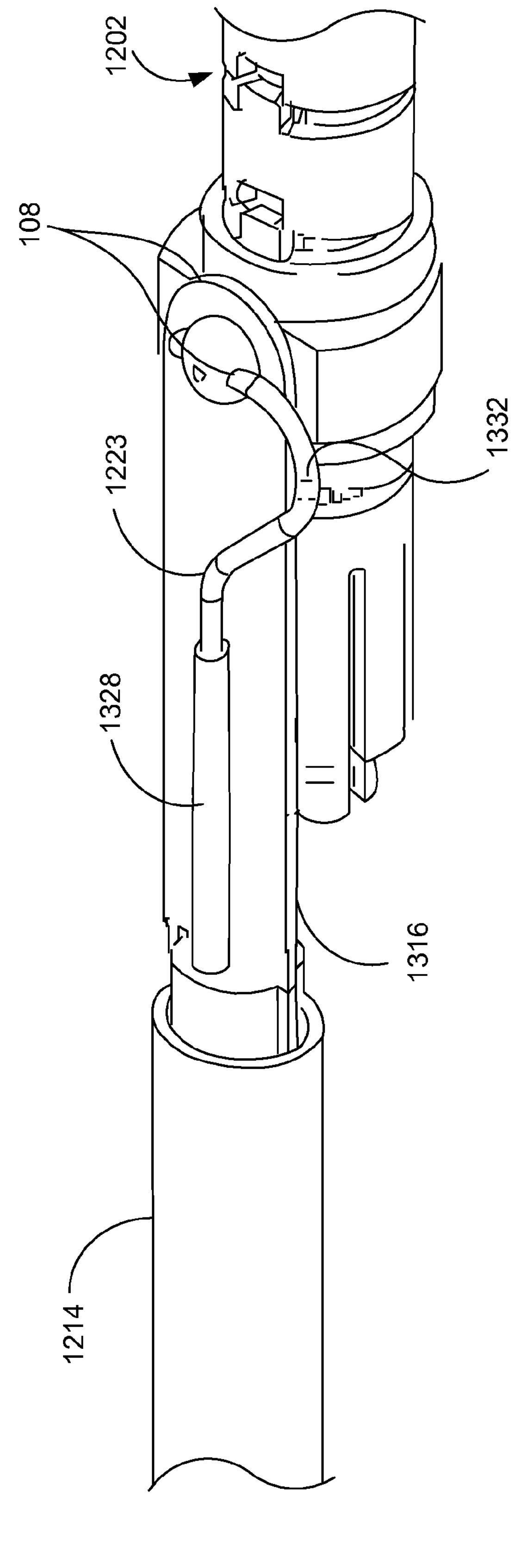

FIG. 13C

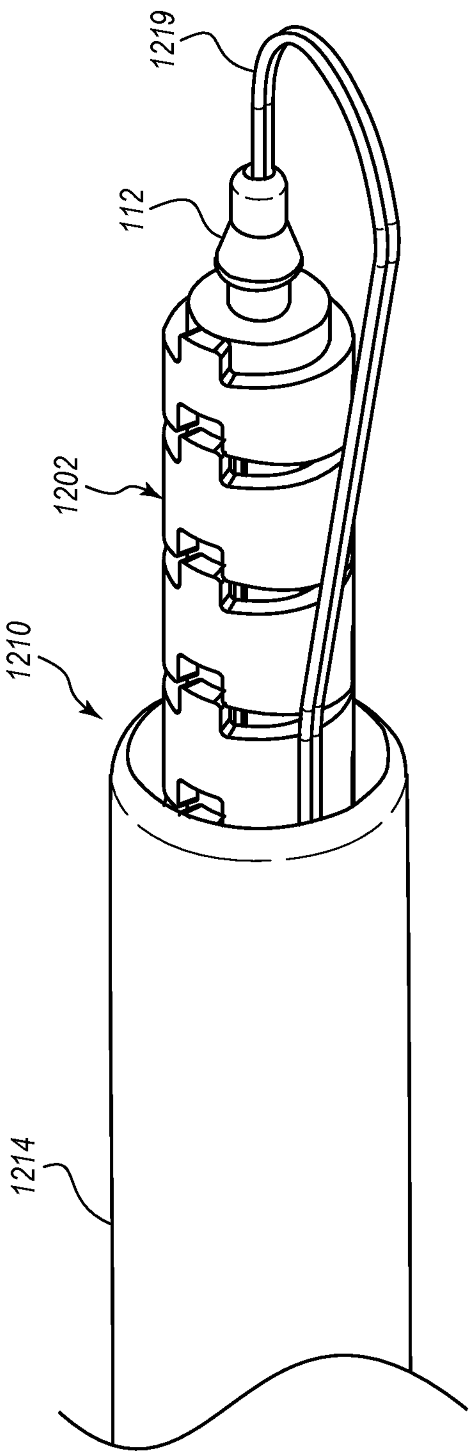

FIG. 13D

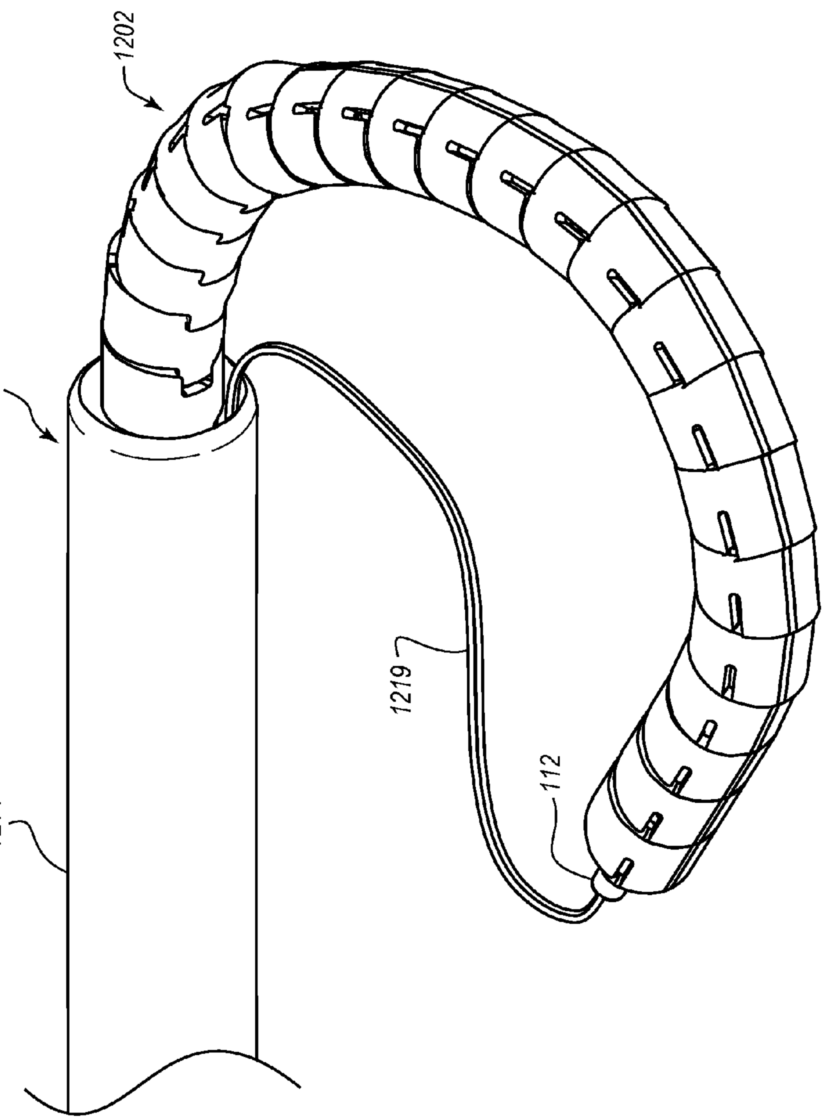

FIG. 13E

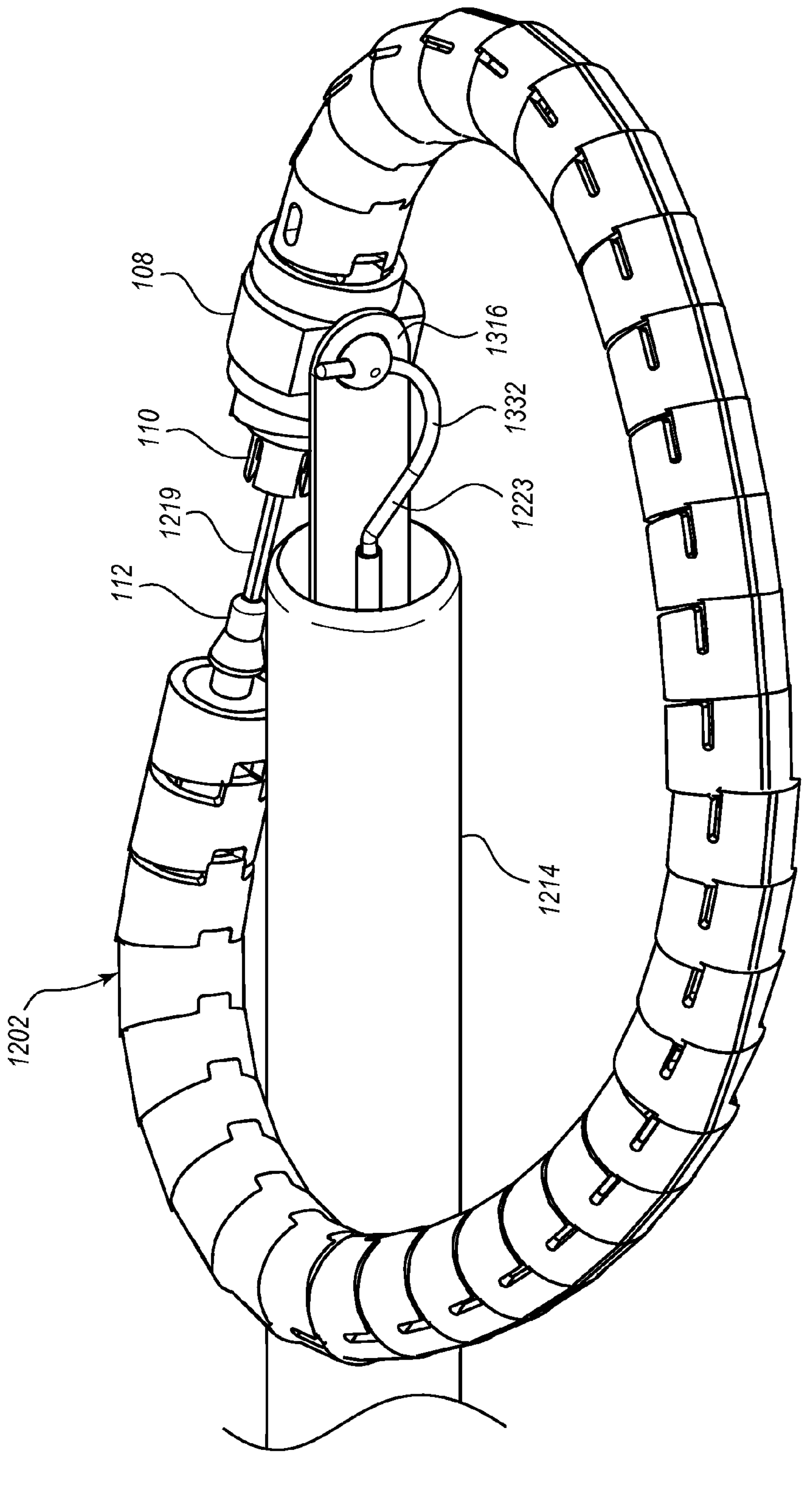

FIG. 13F

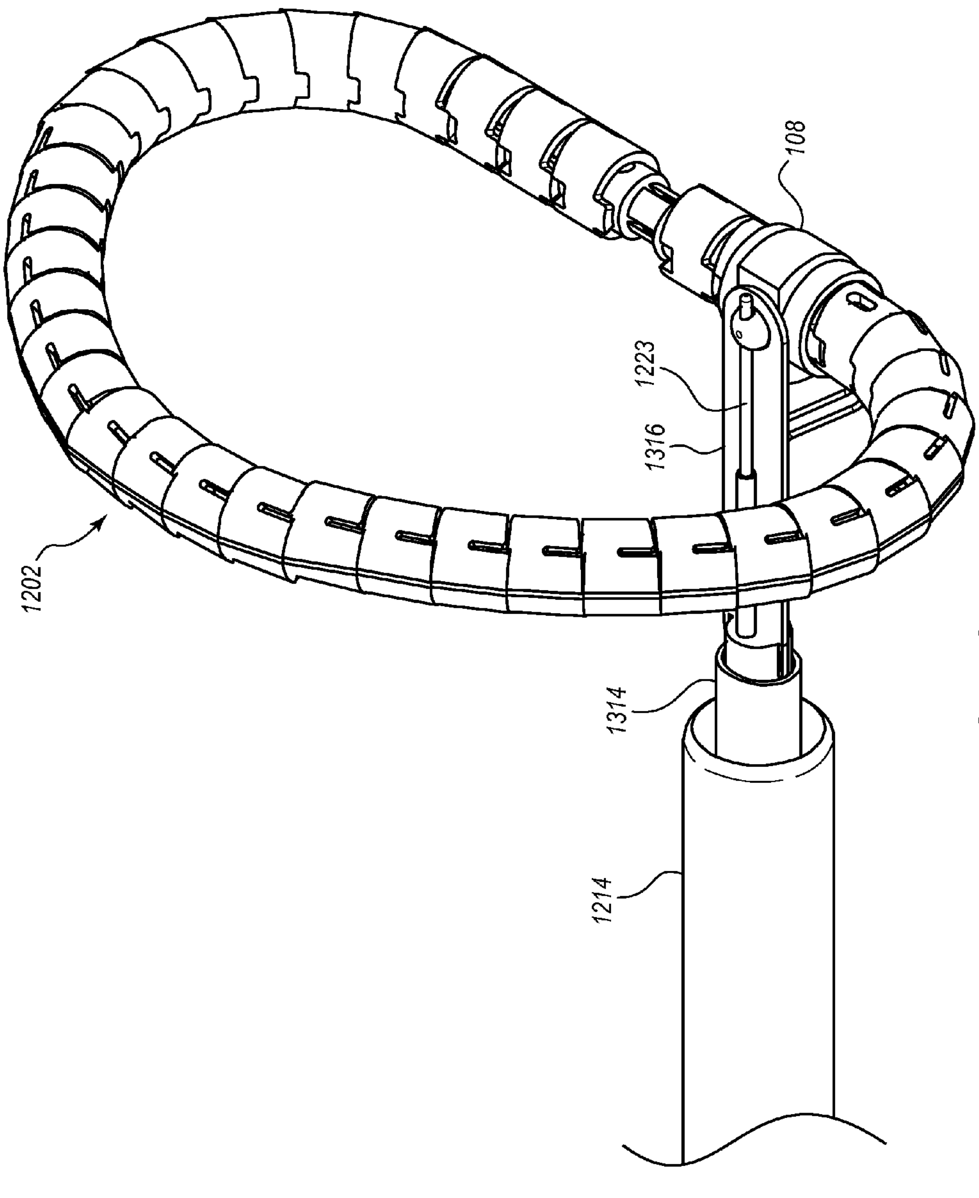

FIG. 13G

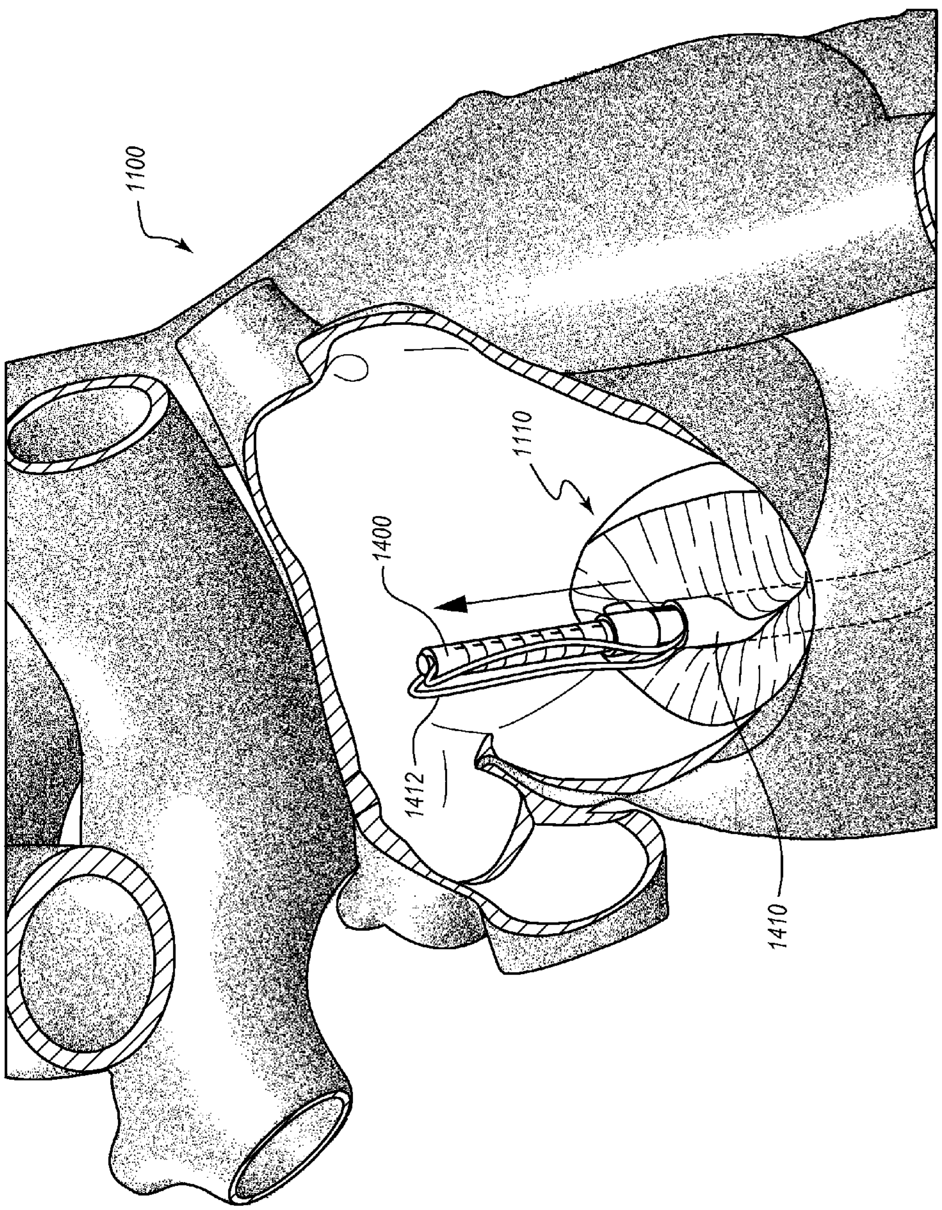

FIG. 14A

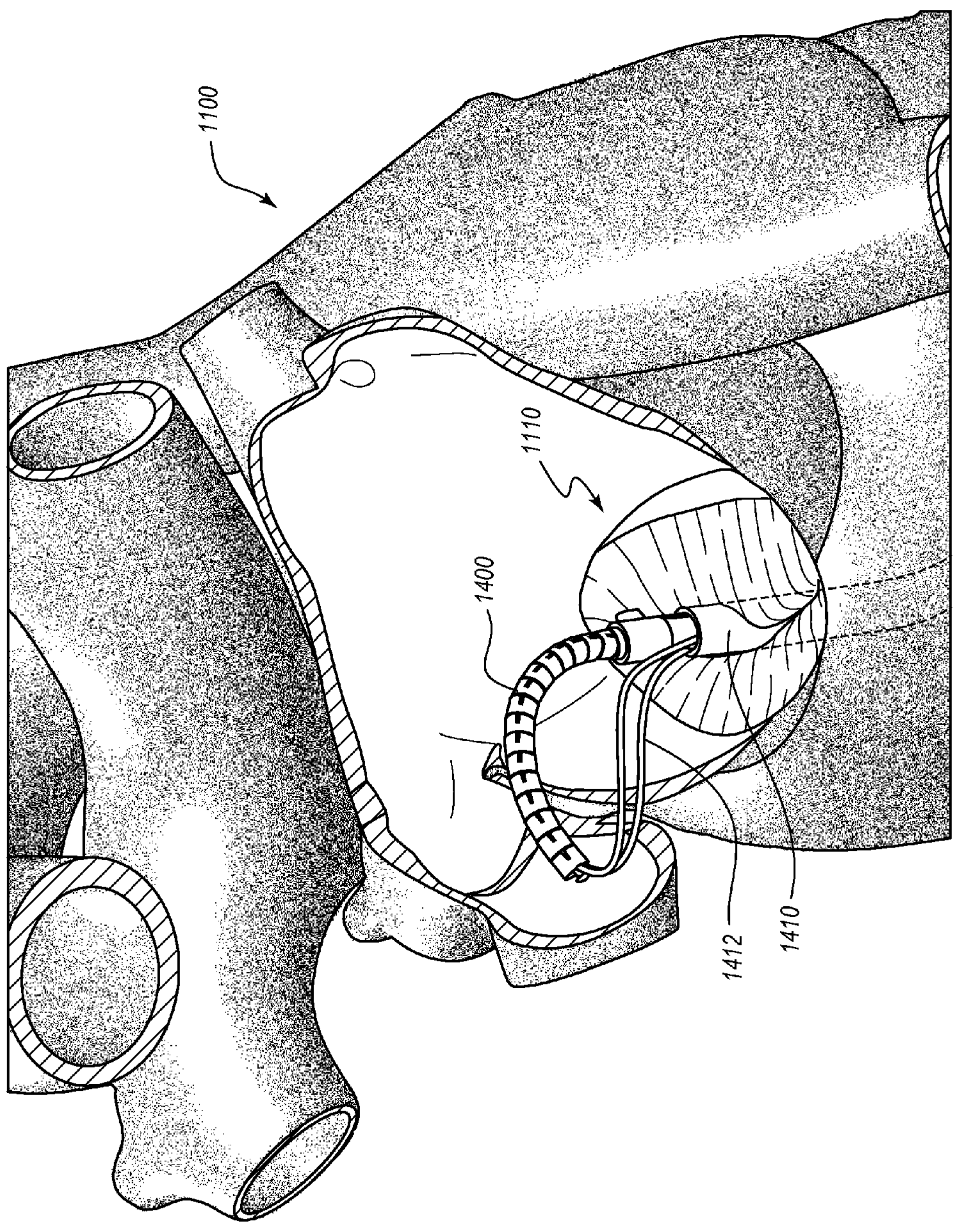

FIG. 14B

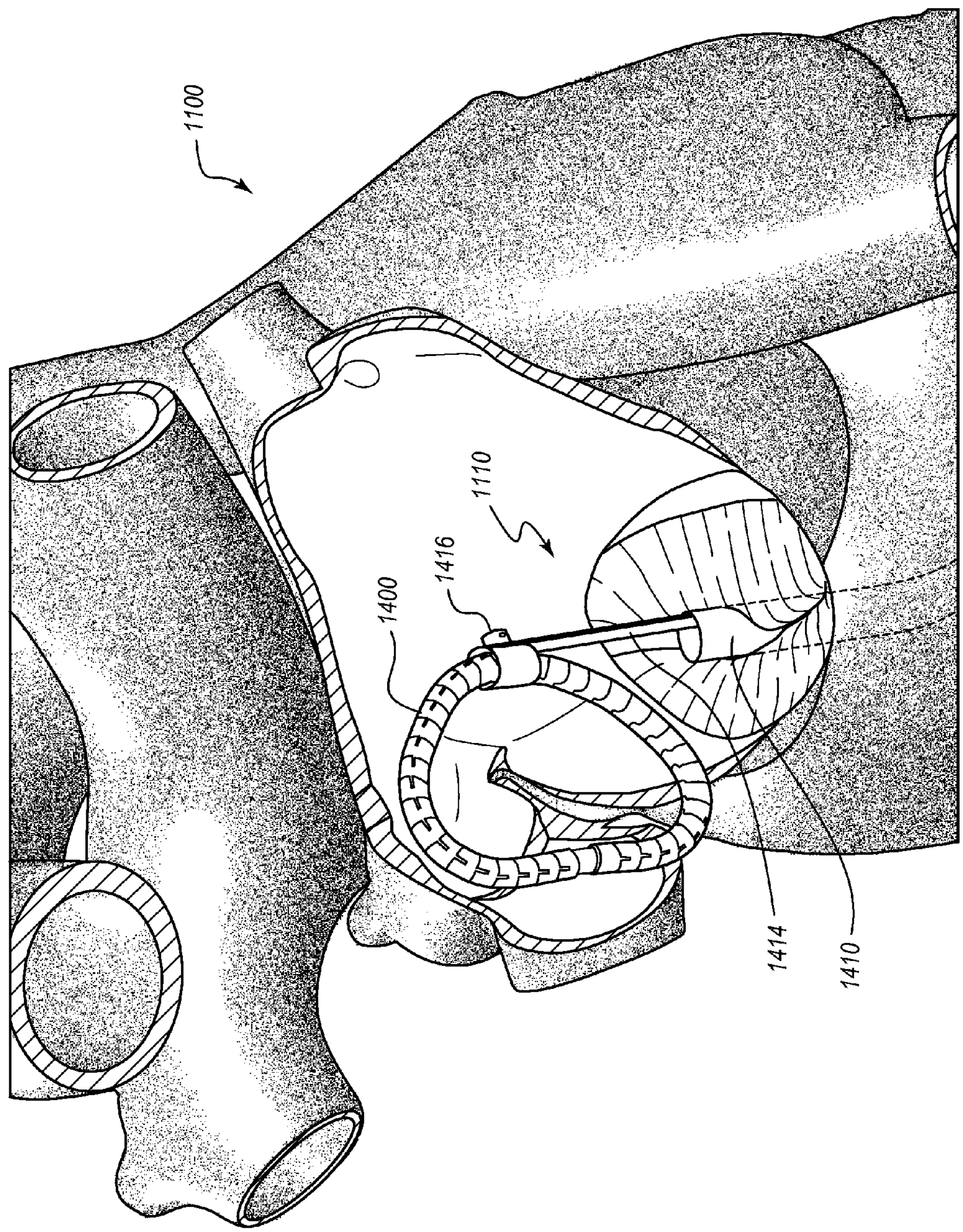

FIG. 14C

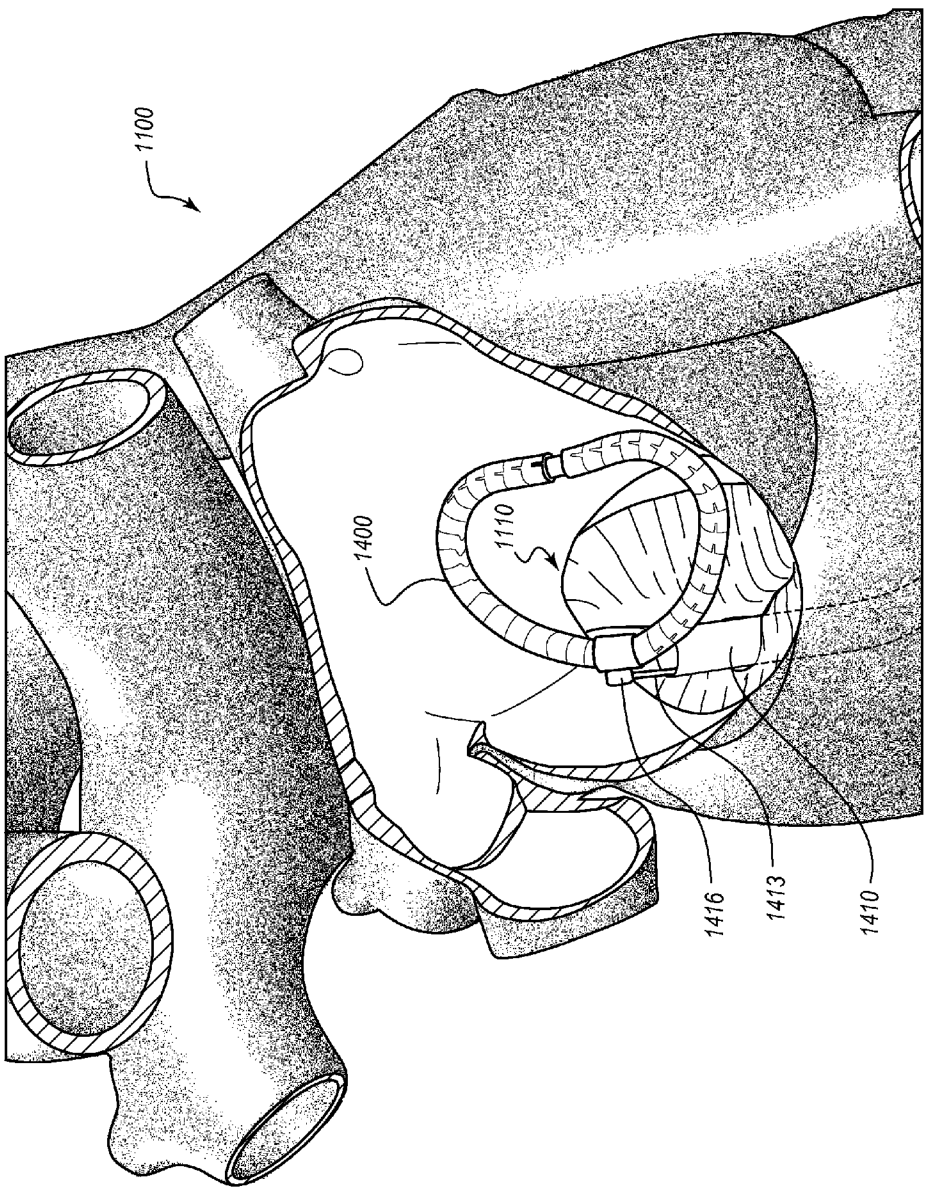

FIG. 14D

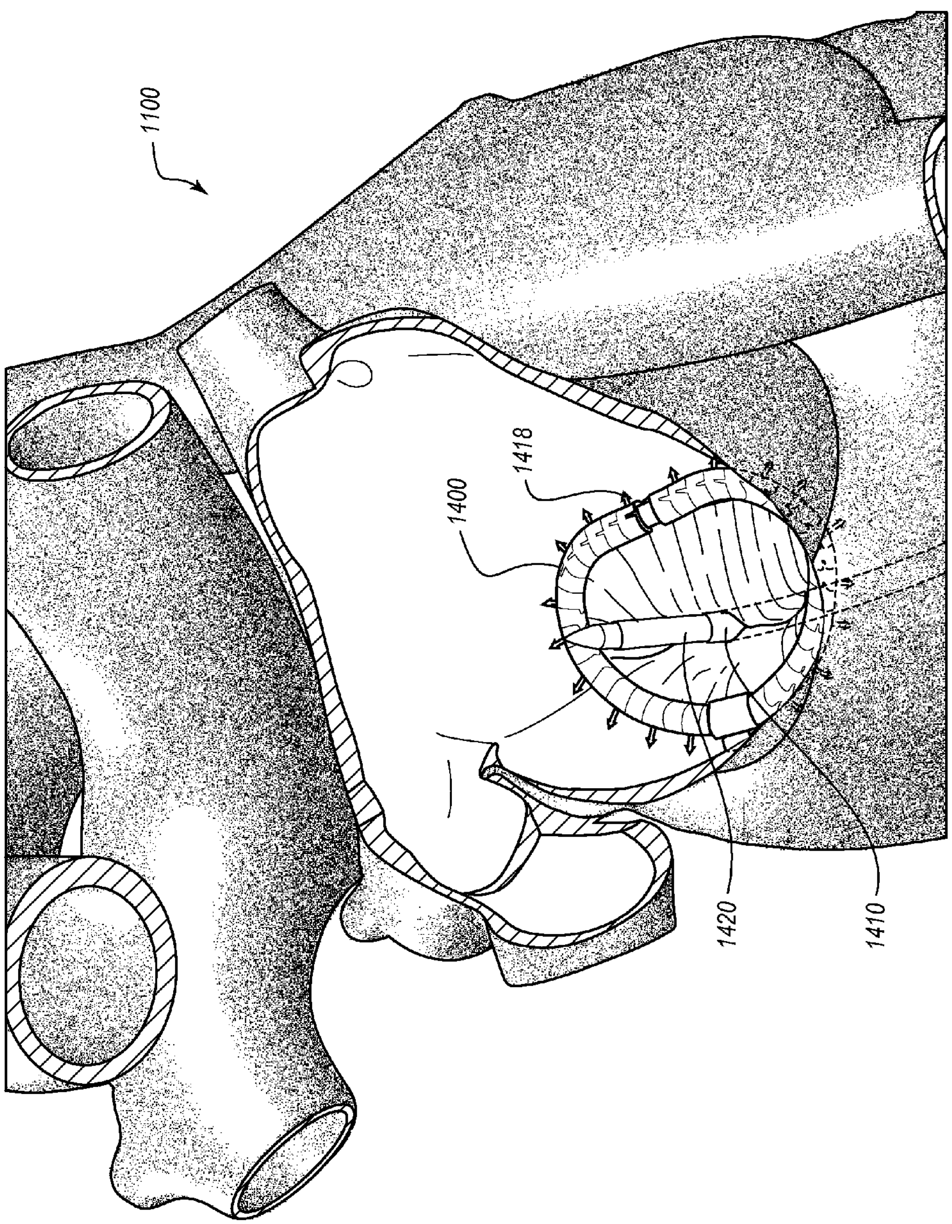

FIG. 14E

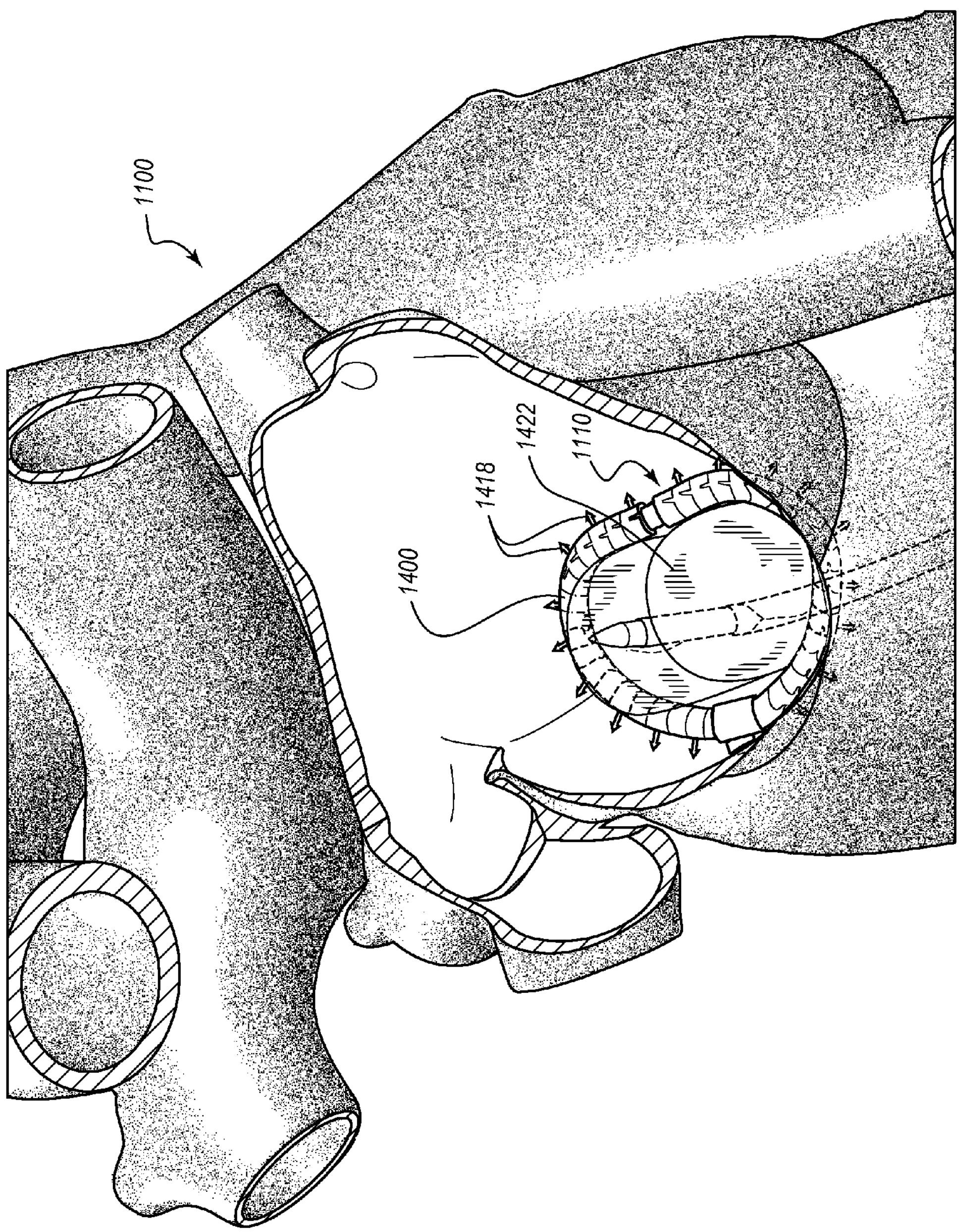

FIG. 14F

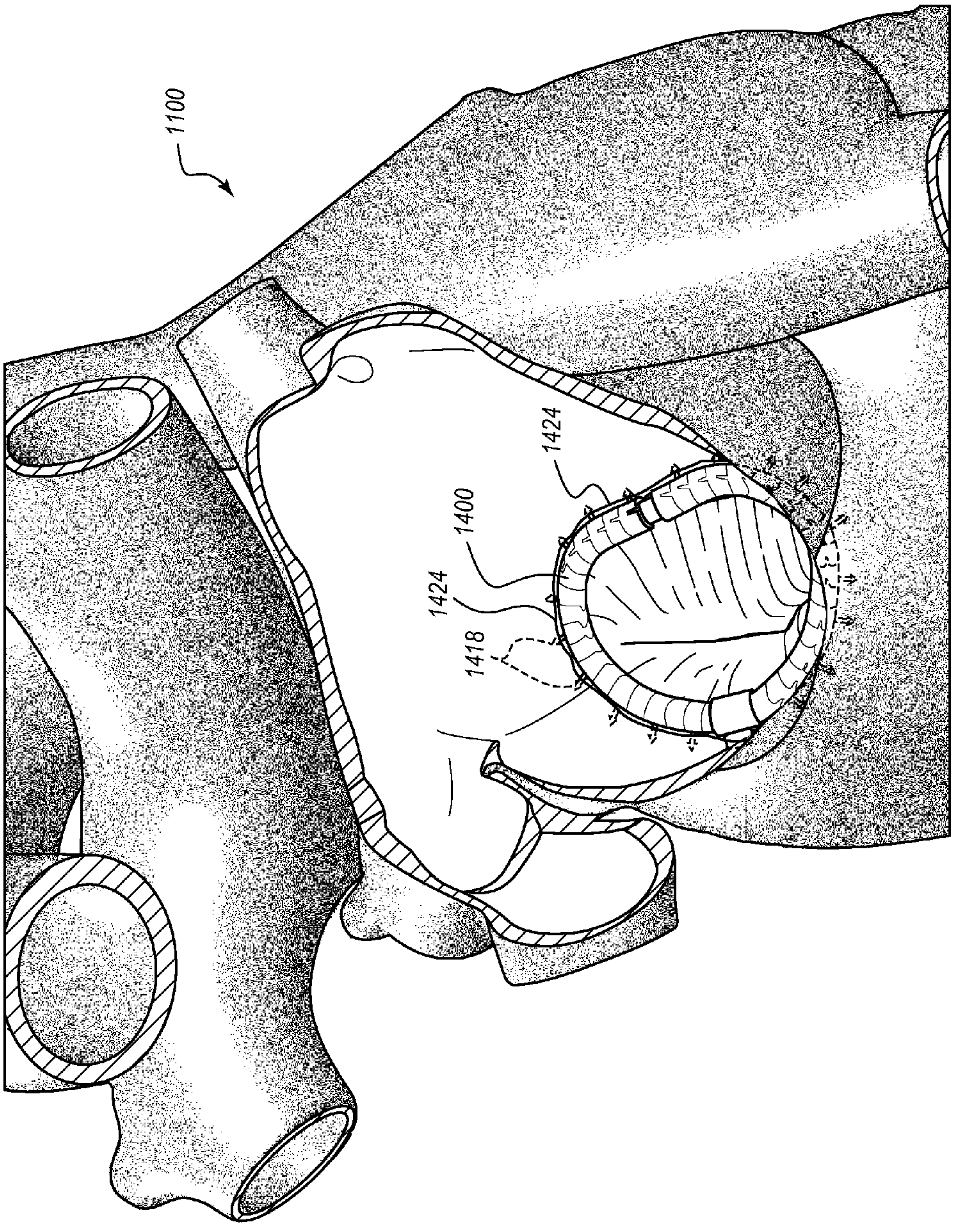

FIG. 14G

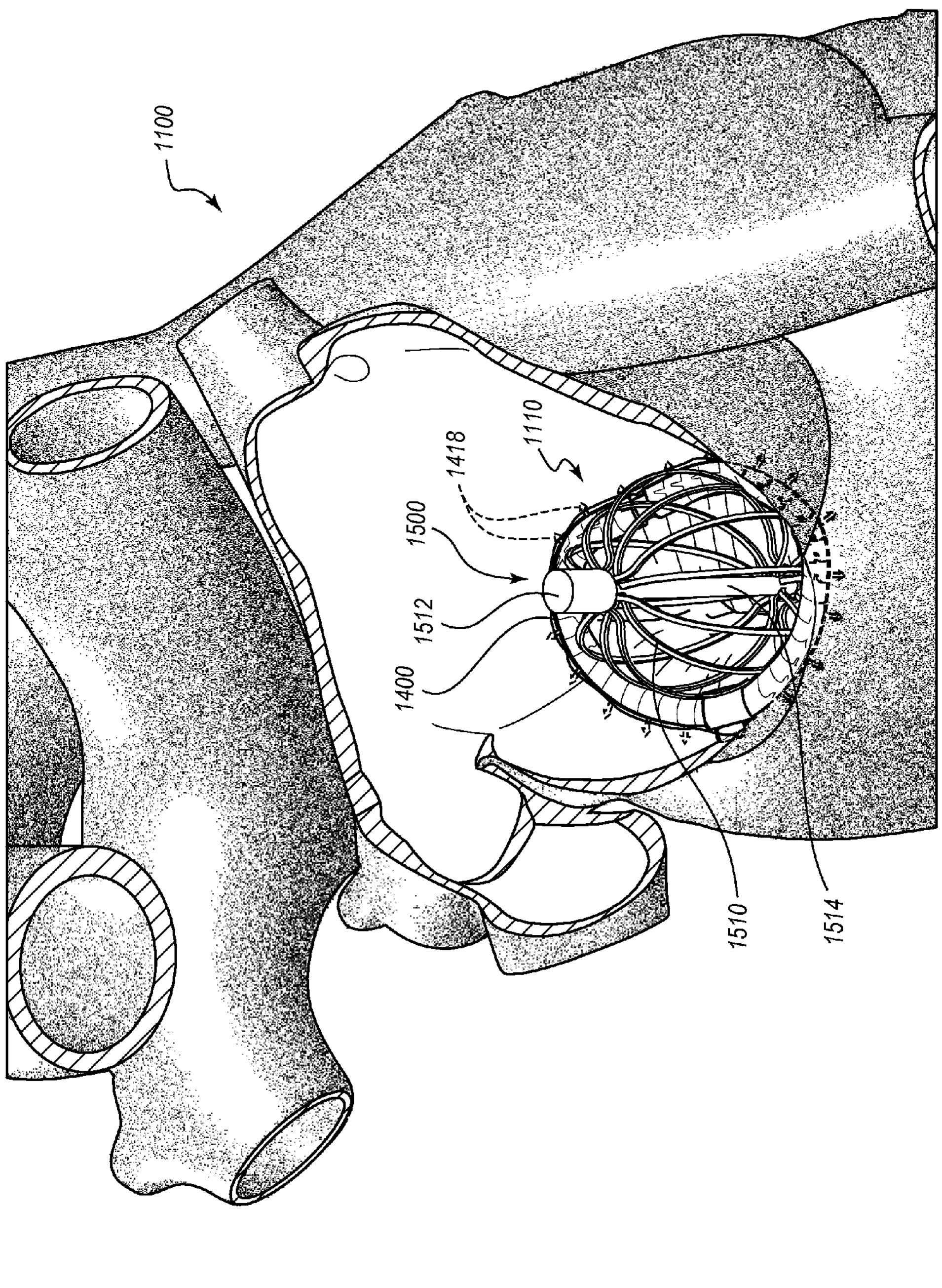

FIG. 15

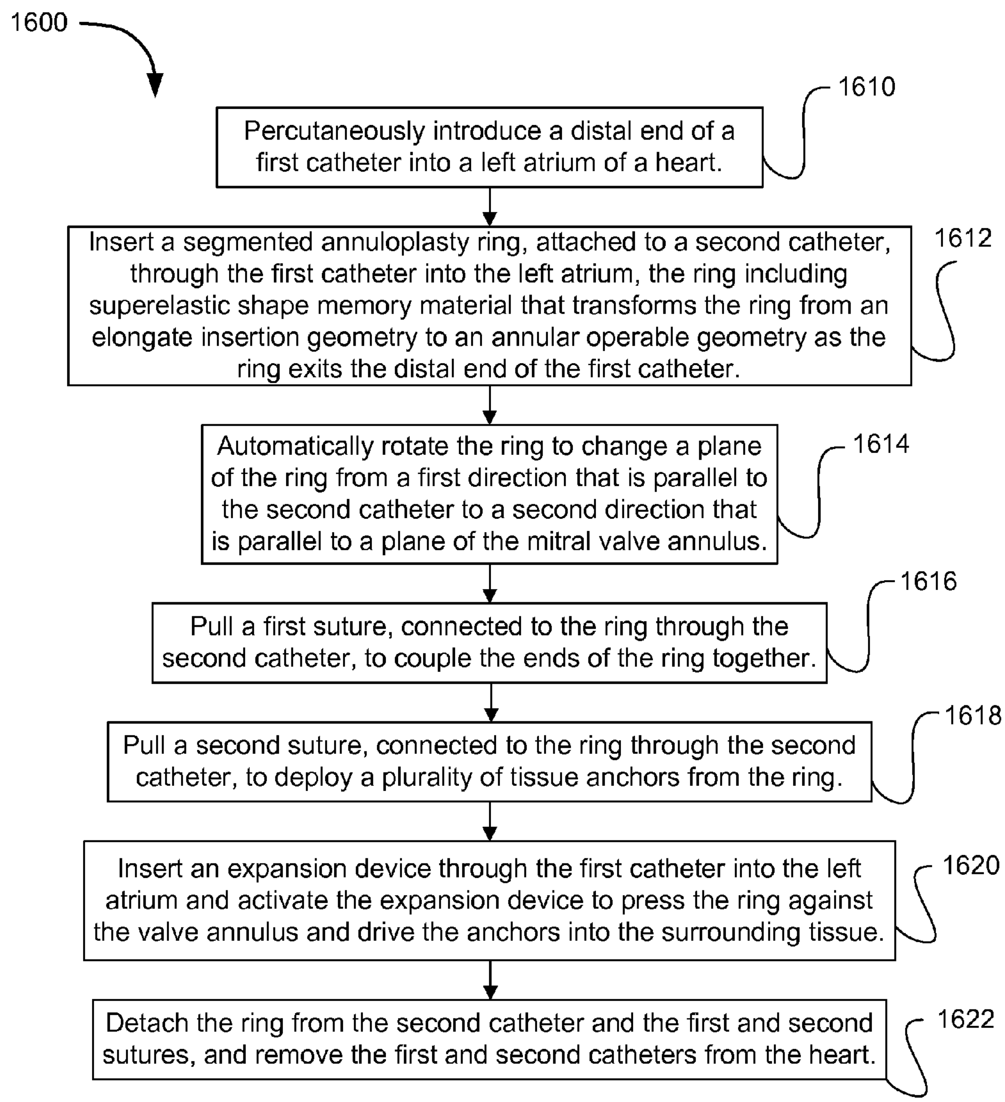
1600
1610
Percutaneously introduce a distal end of a first catheter into a left atrium of a heart.
1612
Insert a segmented annuloplasty ring, attached to a second catheter, through the first catheter into the left atrium, the ring including superelastic shape memory material that transforms the ring from an elongate insertion geometry to an annular operable geometry as the ring exits the distal end of the first catheter.
1614
Automatically rotate the ring to change a plane of the ring from a first direction that is parallel to the second catheter to a second direction that is parallel to a plane of the mitral valve annulus.
1616
Pull a first suture, connected to the ring through the second catheter, to couple the ends of the ring together.
1618
Pull a second suture, connected to the ring through the second catheter, to deploy a plurality of tissue anchors from the ring.
1620
Insert an expansion device through the first catheter into the left atrium and activate the expansion device to press the ring against the valve annulus and drive the anchors into the surrounding tissue.
1622
Detach the ring from the second catheter and the first and second sutures, and remove the first and second catheters from the heart.

FIG. 16A

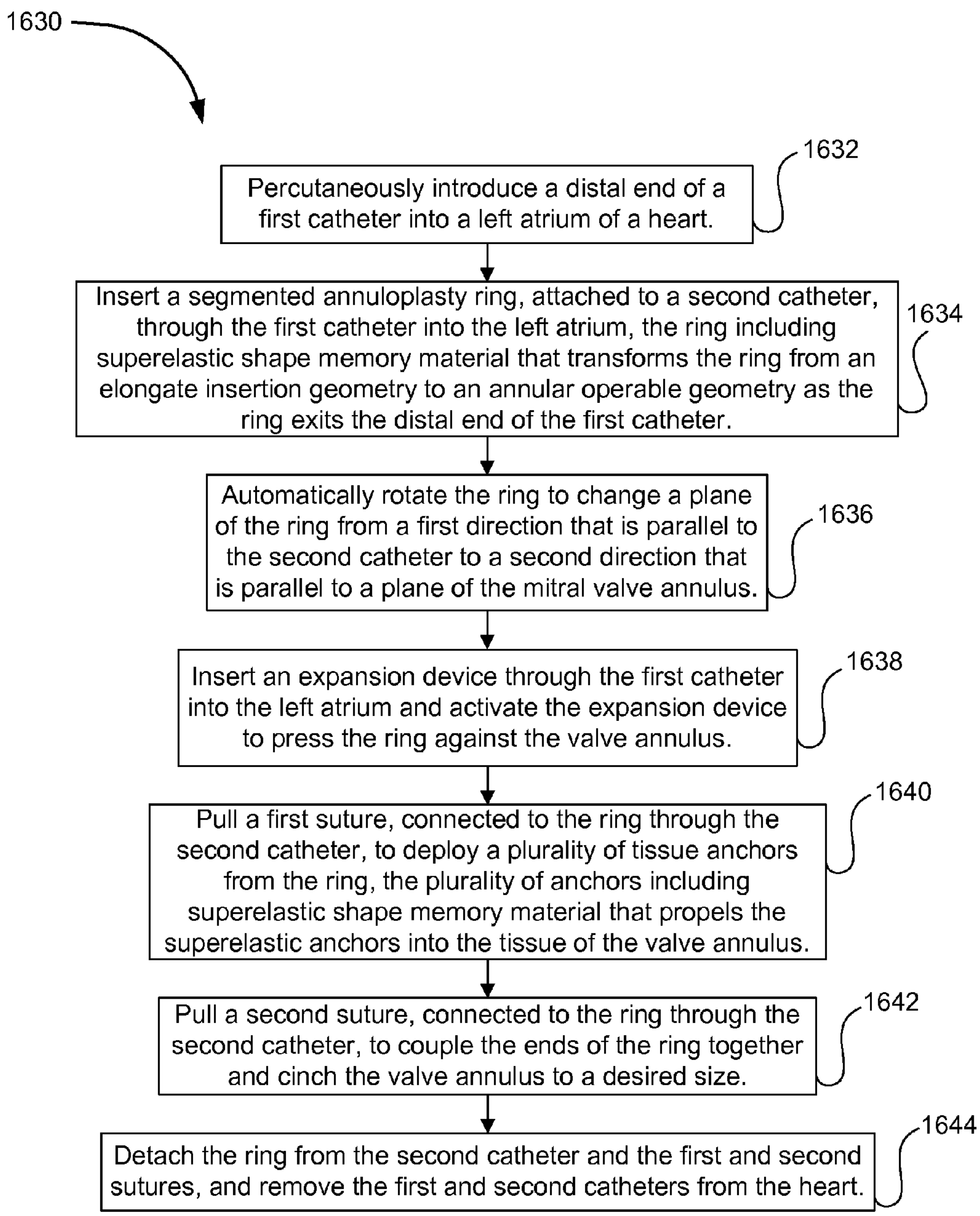
1630
Percutaneously introduce a distal end of a first catheter into a left atrium of a heart.
1632
Insert a segmented annuloplasty ring, attached to a second catheter, through the first catheter into the left atrium, the ring including superelastic shape memory material that transforms the ring from an elongate insertion geometry to an annular operable geometry as the ring exits the distal end of the first catheter.
1634
Automatically rotate the ring to change a plane of the ring from a first direction that is parallel to the second catheter to a second direction that is parallel to a plane of the mitral valve annulus.
1636
Insert an expansion device through the first catheter into the left atrium and activate the expansion device to press the ring against the valve annulus.
1638
Pull a first suture, connected to the ring through the second catheter, to deploy a plurality of tissue anchors from the ring, the plurality of anchors including superelastic shape memory material that propels the superelastic anchors into the tissue of the valve annulus.
1640
Pull a second suture, connected to the ring through the second catheter, to couple the ends of the ring together and cinch the valve annulus to a desired size.
1642
Detach the ring from the second catheter and the first and second sutures, and remove the first and second catheters from the heart.
1644

FIG. 16B

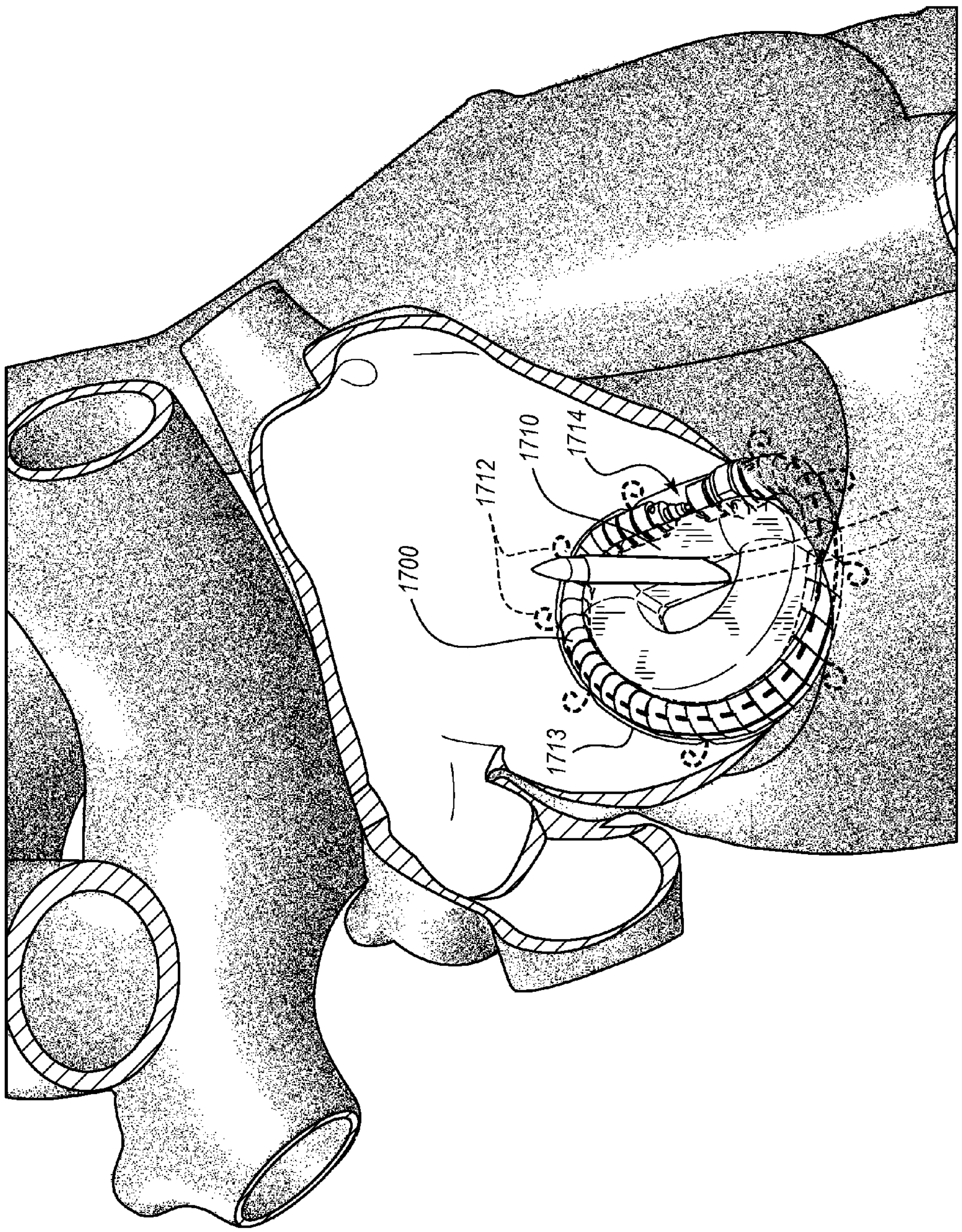

FIG. 17

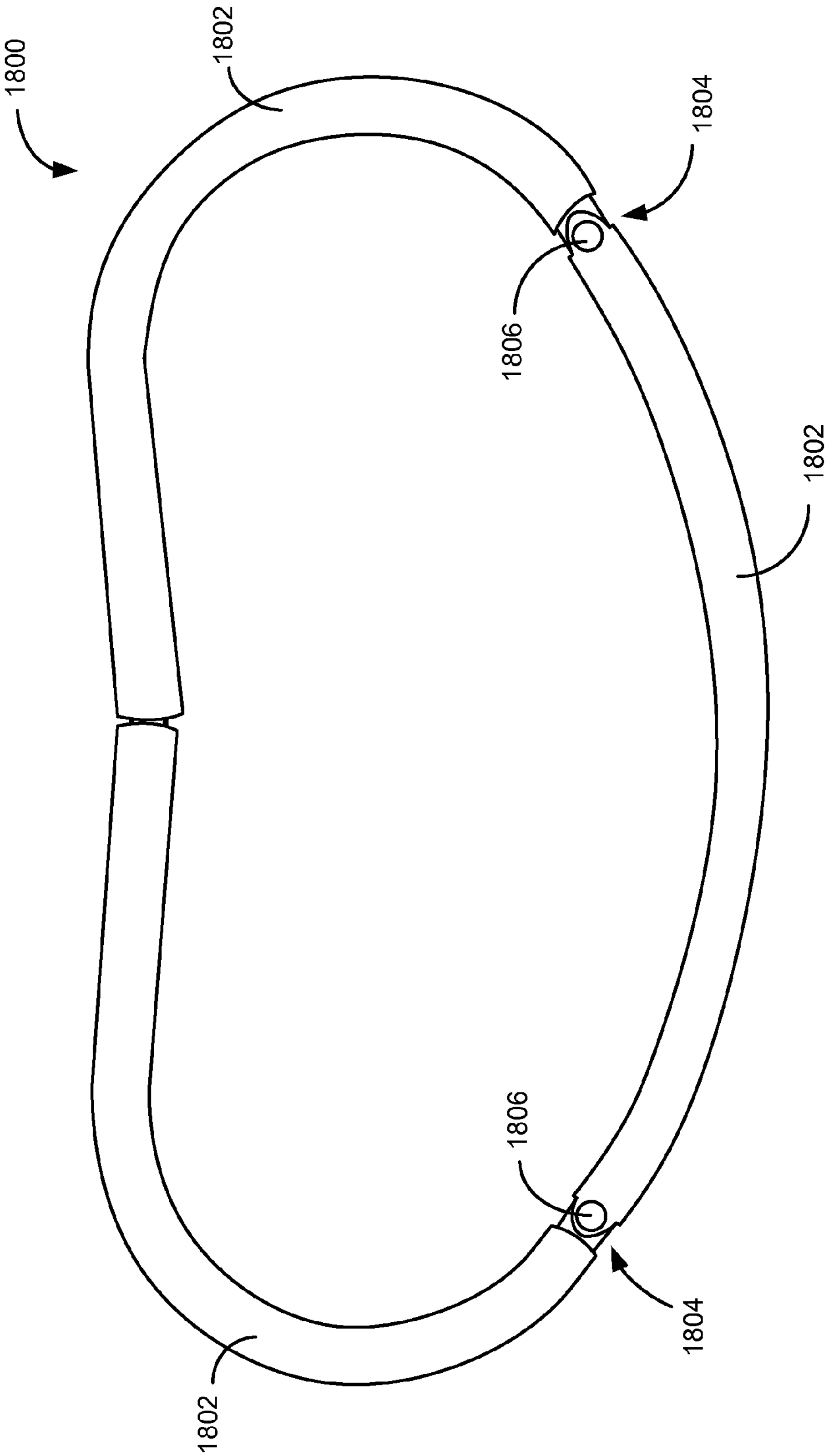

FIG. 18

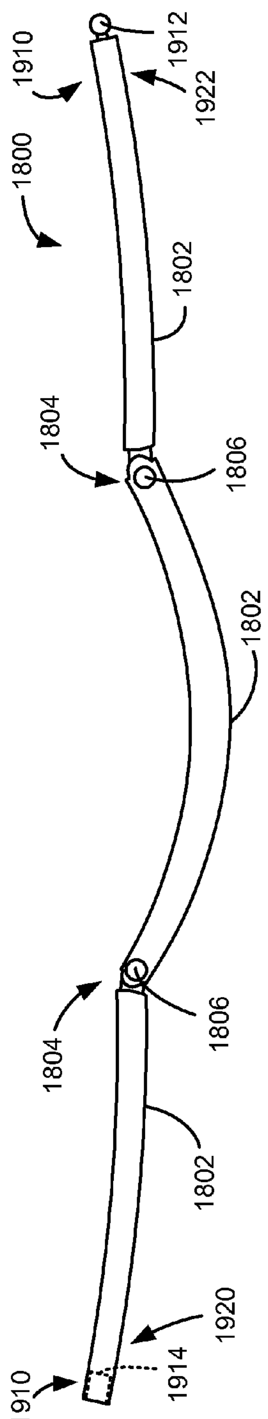

FIG. 19A

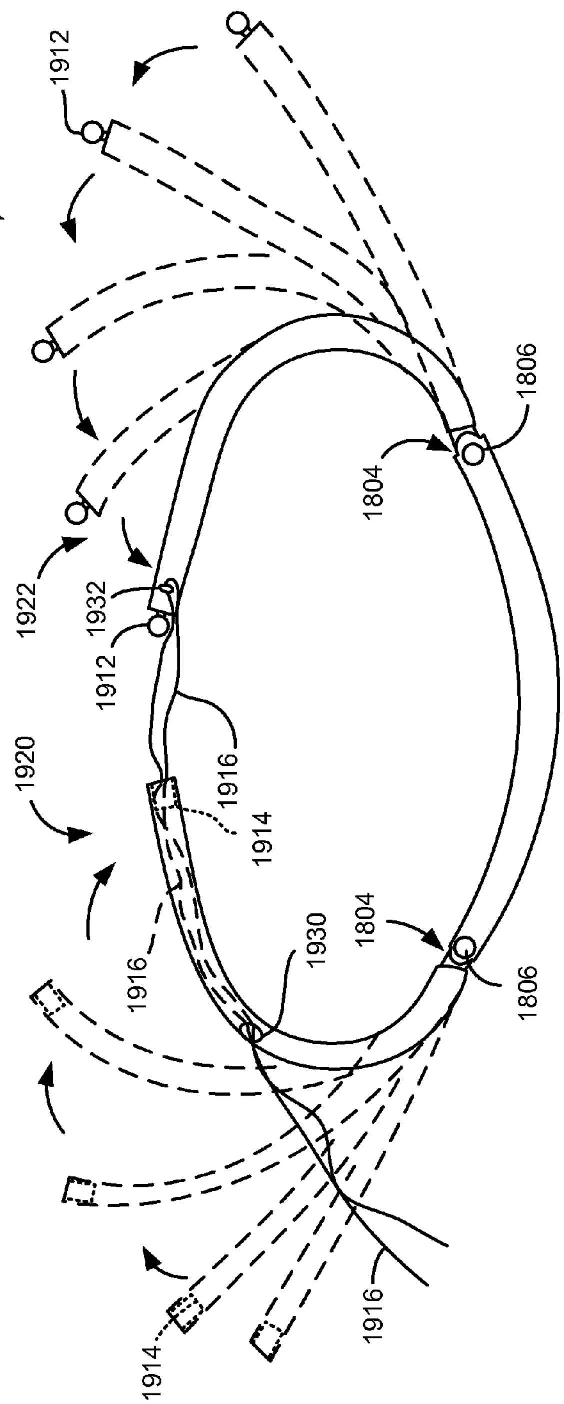

FIG. 19B

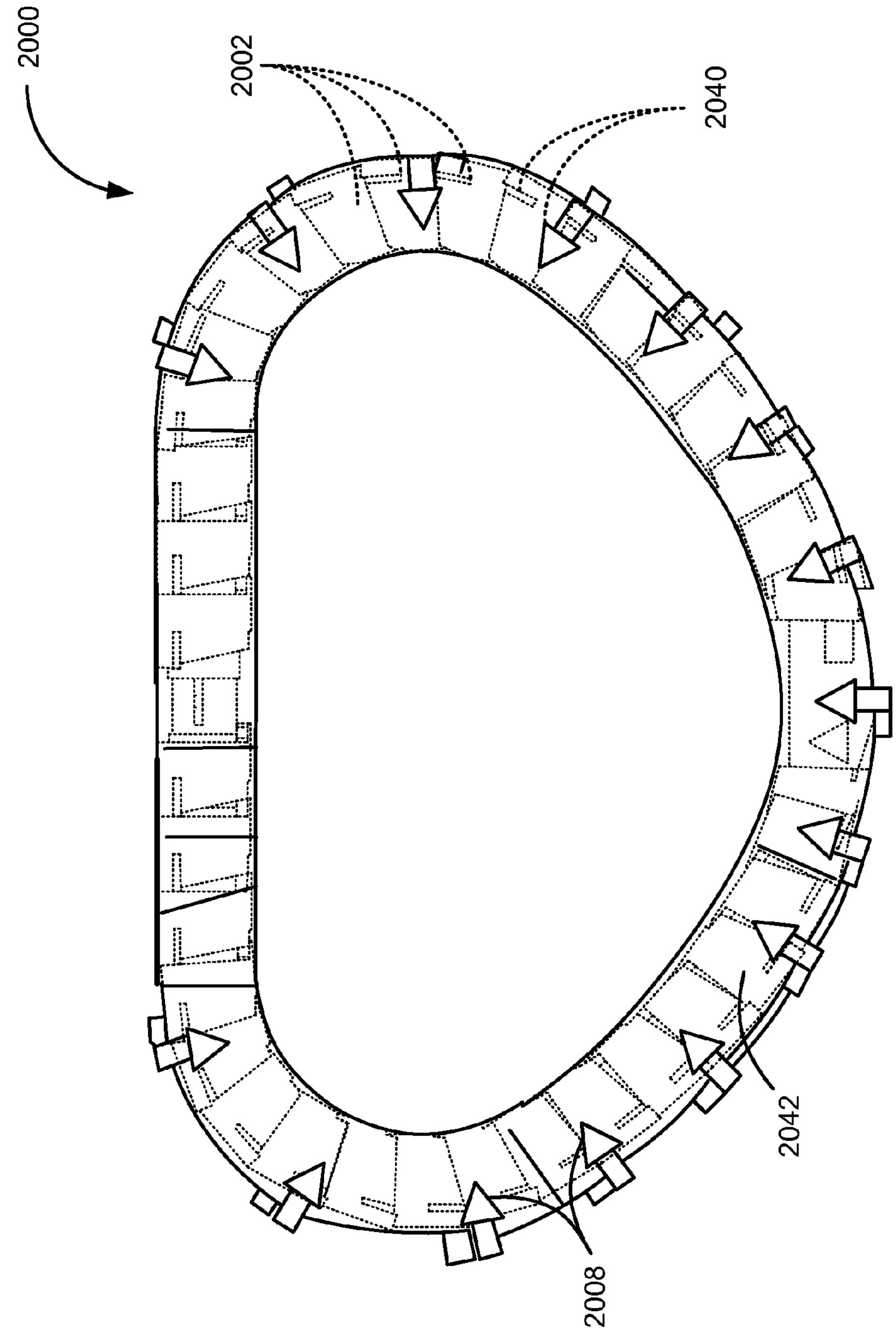

FIG. 20A

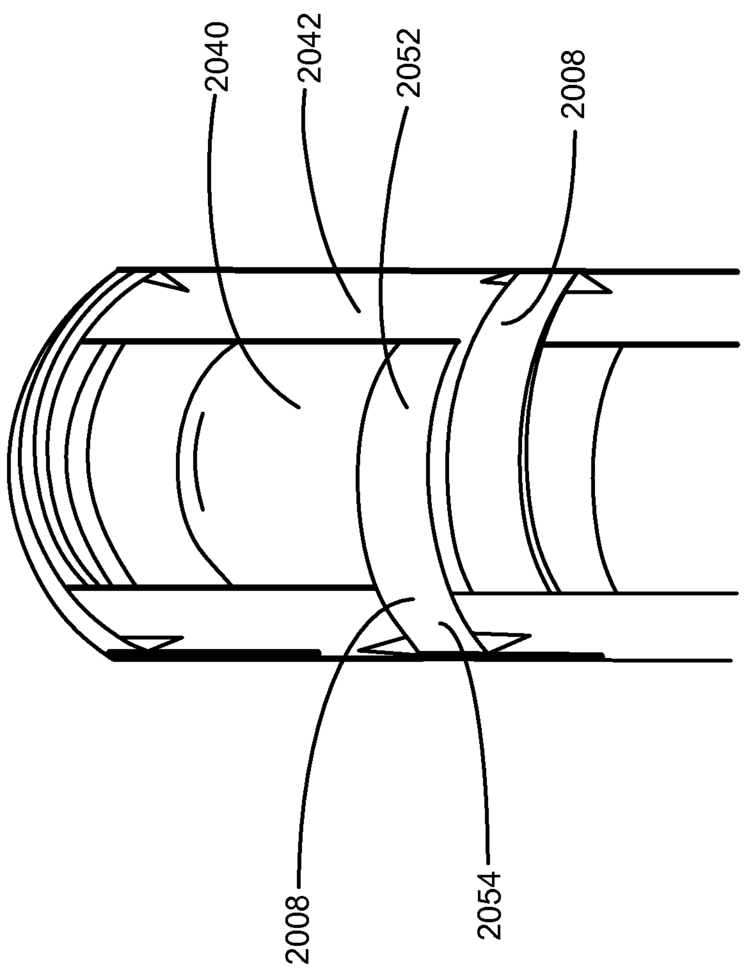

FIG. 20B

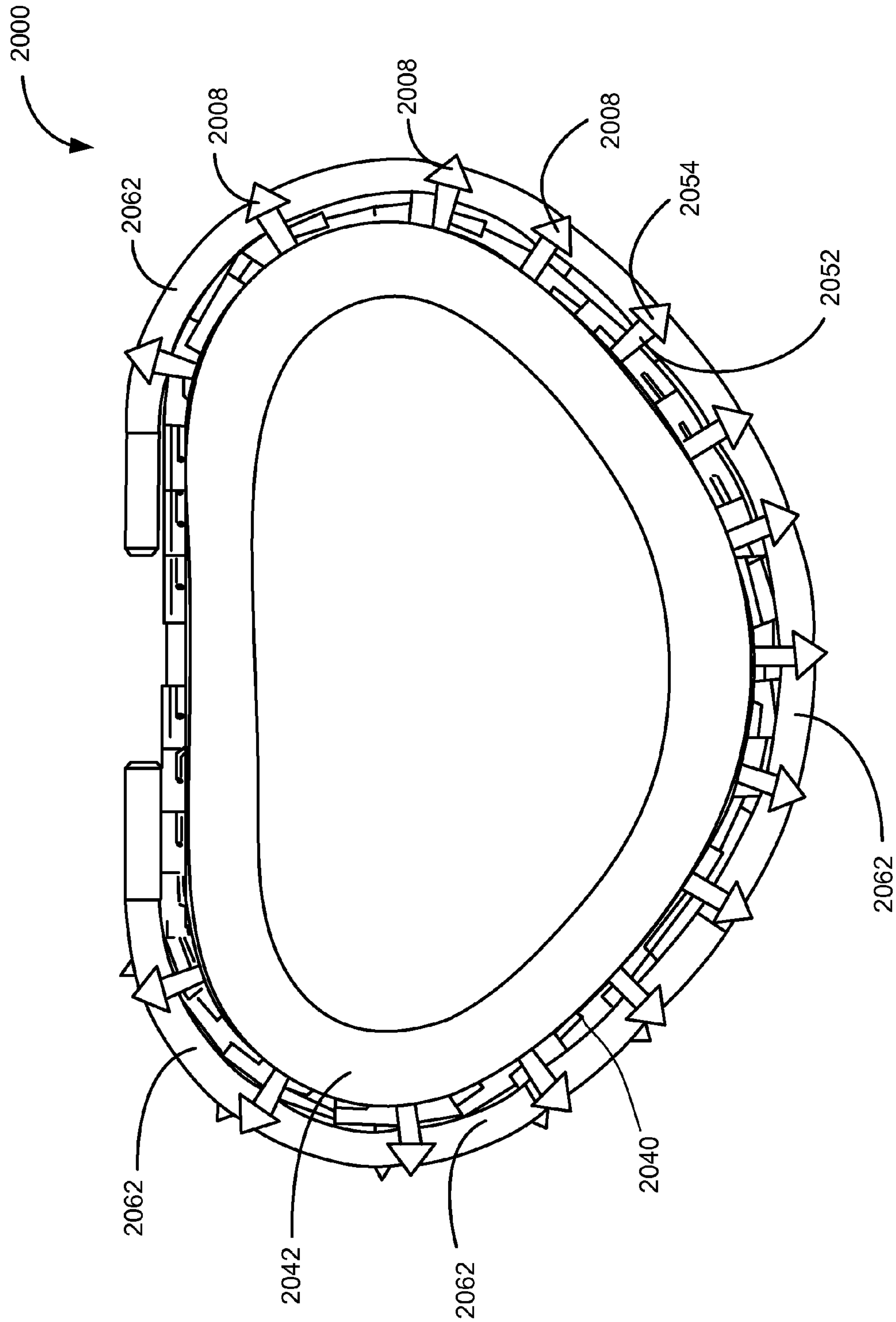

FIG. 20C

PERCUTANEOUS TRANSCATHETER REPAIR OF HEART VALVES

RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 13/198,582, filed Aug. 4, 2011, and titled "PERCUTANEOUS TRANSCATHETER REPAIR OF HEART VALVES." U.S. patent application Ser. No. 13/198,582 claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 61/370,754, filed Aug. 4, 2010, and titled "PERCUTANEOUS DELIVERY OF ANNULOPLASTY RINGS TO HEART VALVES," of U.S. Provisional Patent Application No. 61/383,681, filed Sep. 16, 2010, and titled "PERCUTANEOUS DELIVERY OF ANNULOPLASTY RINGS TO HEART VALVES," and of U.S. Provisional Patent Application No. 61/492,279, filed Jun. 1, 2011, and titled "TRANSCATHETER FIXATION OF ANNULOPLASTY RINGS." Each of the above applications is hereby incorporated herein by reference in its entirety.

TECHNICAL FIELD

The present disclosure relates to treating and repairing heart valves, and specifically to apparatus, systems, and methods for percutaneous transcatheter delivery and fixation of annuloplasty rings to repair heart valves. Disclosed ring embodiments are configured to be delivered through a catheter using, for example, a trans-septal approach, a retrograde approach, or a trans-apical approach.

BACKGROUND INFORMATION

Heart valve defects, such as regurgitation, may be caused by a relaxation of the tissue surrounding a heart valve (e.g., the mitral valve or tricuspid valve). This causes the valve opening to enlarge, which prevents the valve from sealing properly. Such heart conditions are commonly treated by a procedure during which an annuloplasty ring is fixed or secured around the valve. Cinching or securing the tissue to the ring can restore the valve opening to its approximate original size and operating efficiency.

Typically, annuloplasty rings have been implanted during open heart surgery, so that the annuloplasty ring can be sewn into the valve annulus. Open heart surgery is a highly invasive procedure that requires connecting a heart and lung machine (to pump the patient's blood and breathe for the patient), stopping the patient's heart, and cutting open the thoracic cavity and heart organ. The procedure can expose the patient to high risk of infection and may result in a long and difficult recovery. The recovery can be particularly difficult for patients in less than optimal health due to the effects of suffering from a heart valve defect such as regurgitation.

SUMMARY OF THE DISCLOSURE

Disclosed herein are apparatus, systems, and methods for repairing heart valves through percutaneous transcatheter delivery and fixation of annuloplasty rings to heart valves.

In one embodiment, an annuloplasty ring includes an outer hollow member including a plurality of segments. Adjacent segments cooperate with one another to change the outer hollow member from an elongate insertion geometry to an annular operable geometry. The annuloplasty ring also includes an internal anchor member located at least partially within the outer hollow member. The internal anchor member includes a plurality of anchors configured to attach the annuloplasty ring to tissue of a heart valve annulus. The internal anchor member is configured to move the plurality of anchors with respect to a plurality of windows in the outer hollow member to selectively deploy the plurality of anchors through the respective windows.

In certain embodiments, methods are disclosed for percutaneous transcatheter repair of a heart valve using the segmented annuloplasty ring.

In addition, or in other embodiments, a delivery system is disclosed for percutaneous transcatheter delivery of the segmented annuloplasty ring.

BRIEF DESCRIPTION OF THE DRAWINGS

Understanding that drawings depict only certain embodiments and are not therefore to be considered to be limiting in nature, non-limiting and non-exhaustive embodiments of the disclosure are described and explained with additional specificity and detail through the use of the accompanying drawings.

FIG. **1** is a simplified schematic diagram illustrating a perspective view of a segmented annuloplasty ring according to one embodiment.

FIGS. **1**A and **1**B are schematic diagrams illustrating a shape memory hypotube cut to form a plurality of segments for use as an outer tube of a segmented annuloplasty ring according to one embodiment.

FIG. **1**C is a schematic diagram illustrating a cutting pattern used for laser processing the hypotube shown in FIGS. **1**A and **1**B.

FIG. **1**D is a schematic diagram illustrating the shape memory hypotube shown in FIGS. **1**A and **1**B in an annular (D-shaped) operable geometry.

FIG. **2**A is a simplified schematic diagram illustrating a side view of an internal anchor ribbon including the curved anchors shown in FIG. **1** according to one embodiment.

FIG. **2**B is a schematic diagram illustrating a top view of the anchors cut into the internal anchor ribbon shown in FIG. **2**A in the elongate insertion geometry according to one embodiment.

FIG. **2**C is a schematic diagram illustrating a side view of the internal anchor ribbon in the elongate insertion geometry and the anchors in a curled or curved deployed configuration according to one embodiment.

FIG. **2**D is a schematic diagram illustrating a top view of an internal glide ribbon shown in FIG. **2**A in an elongate insertion geometry according to one embodiment.

FIG. **2**E is a schematic diagram illustrating a side view of the internal glide ribbon shown in FIG. **2**D.

FIGS. **3**A and **3**B are simplified schematics illustrating cross-section side views of an annuloplasty ring before (FIG. **3**A) and after (FIG. **3**B) deployment of the anchors shown in FIG. **2**C according to one embodiment.

FIG. **4**A is a schematic diagram illustrating a perspective view of a portion of the annuloplasty ring shown in FIGS. **3**A and **3**B with a deployed curved anchor according to one embodiment.

FIG. **4**B is a schematic diagram illustrating a side view of a portion of the annuloplasty ring shown in FIG. **4**A.

FIG. **5** is a simplified schematic diagram illustrating a side view of the internal glide ribbon shown in FIG. **2**A used as a selectively adjustable member according to one embodiment.

FIGS. **5**A, **5**B, and **5**C are schematic diagrams of circuitry for using RF induction to activate the shape memory material of the internal glide ribbon according to one embodiment.

FIG. **6**A is a schematic diagram illustrating a perspective view of a segmented annuloplasty ring including a plurality of linear anchors according to one embodiment.

FIG. **6**B is a schematic diagram illustrating a side view of a portion of the annuloplasty ring shown in FIG. **6**A.

FIG. **7** is a simplified schematic diagram illustrating a side view of an internal anchor member including linear anchors according to one embodiment.

FIG. **8**A is a schematic diagram illustrating an enlarged perspective view of a single-barbed anchor of a percutaneous transcatheter annuloplasty ring in an affixation configuration according to one embodiment.

FIG. **8**B is a schematic diagram of an enlarged perspective view of a dual-barbed anchor of a percutaneous transcatheter annuloplasty ring in an affixation configuration according to one embodiment.

FIG. **9** is a simplified schematic diagram illustrating a side view of the internal anchor member shown in FIG. **7** and a selectively adjustable member according to one embodiment.

FIG. **10** is a schematic diagram illustrating a partial cross-sectional view of the selectively adjustable member shown in FIG. **9** according to one embodiment.

FIG. **11**A is a schematic diagram illustrating a trans-septal approach for endovascular delivery of an annuloplasty ring to the mitral valve of a heart according to one embodiment.

FIG. **11**B is a schematic diagram illustrating an example retrograde approach of an annuloplasty ring to the mitral valve of a heart according to another embodiment.

FIG. **11**C is a schematic diagram illustrating an example trans-apical approach of an annuloplasty ring to the mitral valve of a heart according to another embodiment.

FIGS. **12**A and **12**B are schematic diagrams illustrating a delivery system for implanting a segmented annuloplasty ring within a heart according to certain embodiments.

FIGS. **13**A, **13**B, **13**C, **13**D, **13**E, **13**F, and **13**G are schematic diagrams illustrating the front of the delivery system shown in FIG. **12**A according to certain embodiments.

FIGS. **14**A, **14**B, **14**C, **14**D, **14**E, **14**F, and **14**G are schematic diagrams illustrating perspective, partially cross-section views of a heart during the introduction and affixation of a segmented annuloplasty ring to the annulus of the mitral valve according to certain embodiments.

FIG. **15** is a schematic diagram illustrating a perspective, partially cross-section view of the heart during the introduction and affixation of the segmented annuloplasty ring using an expandable cage or basket, instead of the balloon shown in FIG. **14**F, according to one embodiment.

FIG. **16**A is a flowchart of a method for repairing a defective heart valve according to one embodiment.

FIG. **16**B is a flowchart of a method for repairing a defective heart valve according to another embodiment.

FIG. **17** is a schematic diagram illustrating a perspective, partially cross-section view of the heart during the introduction and affixation of a segmented annuloplasty ring according to another embodiment.

FIG. **18** is a schematic diagram of a percutaneous transcatheter annuloplasty ring in an annular operable geometry according to one embodiment.

FIG. **19**A is a schematic diagram illustrating the percutaneous transcatheter annuloplasty ring of FIG. **18** in an insertion geometry according to one embodiment.

FIG. **19**B is a schematic diagram of the percutaneous transcatheter annuloplasty ring transitioning from the insertion geometry shown in FIG. **19**A to the operable geometry shown in FIG. **18** according to one embodiment.

FIG. **20**A is a schematic diagram illustrating a percutaneous transcatheter annuloplasty ring according to another embodiment.

FIG. **20**B is a schematic diagram illustrating an enlarged side view of the annuloplasty ring of FIG. **20**A according to one embodiment.

FIG. **20**C is a schematic diagram of the annuloplasty ring of FIG. **20**A with the anchors in an affixation configuration protruding away from the annuloplasty ring according to one embodiment.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

While there are flexible rings currently on the market, surgeons generally prefer rigid and semi-rigid rings for valve repair to treat ischemic and functional mitral valve regurgitation. Rigid and semi-rigid rings, unfortunately, do not lend themselves to being delivered into the heart through a catheter. The present disclosure provides systems and methods for repairing heart valves through percutaneous transcatheter delivery and fixation of annuloplasty rings to heart valves. The embodiments of annuloplasty rings can be configured in both an elongate insertion geometry that can be inserted into a catheter tube and an operable geometry providing a curved and rigid or semi-rigid annular shape.

In certain embodiments, an annuloplasty ring is delivered percutaneously to the mitral and/or tricuspid valve annulus of the heart. The disclosed embodiments apply, for example, to trans-septal, retrograde, or trans-apical approaches for delivering annuloplasty rings to an annulus of a heart valve. For delivery of rings into the mitral valve, percutaneous delivery may use a retrograde approach from the femoral artery, an antegrade approach via a trans-septal entry, or a trans-apical approach through the base or apex of the heart through the left ventricle to the left atrium. Delivery of rings to the tricuspid valve may include an approach from the inferior or superior vena cava.

Certain annuloplasty rings disclosed herein are small and flexible enough to be percutaneously delivered, but can be put into a rigid or semi-rigid ring shape and then securely anchored into the heart valve annulus without having to open up the chest. Disclosed embodiments include segmented annuloplasty rings, delivery systems, and methods for anchoring and cinching the annuloplasty ring around the valve annulus.

Example Ring Embodiments with Curved Anchors

FIG. **1** is a simplified schematic diagram illustrating a perspective view of a segmented annuloplasty ring **100** according to one embodiment. The segmented annuloplasty ring **100** includes a plurality of segments **102**, a plurality of anchors **104**, a ring closure lock **106**, and a pivot **108**. In FIG. **1**, as well as in other embodiments disclosed herein, the plurality of segments **102** are arranged in a “D-shape” in the operable geometry (e.g., when implanted around the annulus). The D-shaped ring **100** has a certain geometrical ratio that is in conformance with the anatomical geometry of the human mitral valve annulus. For example, as discussed below with respect to FIG. **1**D, the ratio in certain embodiments of the anterior-posterior (A-P) distance to the commissure-commissure (C-C) distance of the ring **100** when implanted is in a range between about 0.60 and about 0.70. In one embodiment, the implanted ratio of the A-P distance to the C-C distance is about 0.62. Artisans will recognize from the disclosure herein, however, that other operable geometries may also be used. For example, circular or oval operable geometries may be used.

In addition to the operable geometry, the plurality of segments **102** allow the ring **100** to be placed in an elongate insertion geometry such that the ring **102** can be inserted through a catheter into the heart. As discussed in detail below, in certain embodiments, the segmented annuloplasty ring **100** includes a shape memory (e.g., Nitinol) hypotube into which the plurality of segments **102** are laser cut. The shape memory hypotube is heat set to a "memorized" annular shape (e.g., the D-shaped operable geometry). The shape memory hypotube is superelastic such that applying sufficient stress places the plurality of segments **102** into the elongate insertion geometry and releasing the stress allows the plurality of segments **102** to resume the D-shaped operable geometry.

The plurality of anchors **104** are configured to secure the segmented annuloplasty ring **100** to the annulus of the heart valve. In certain embodiments, the anchors **104** are sufficient such that additional suturing of the segmented annuloplasty ring **100** to the valve annulus is not needed. In FIG. **1**, the anchors **104** are curved in the illustrated deployed configuration. Anchors in other embodiments may include other shapes, such as linear or helical deployed configurations. In certain embodiments, the anchors **104** include a shape memory material (e.g., Nitinol) that is heat set to a deployed configuration (e.g., linear, helical, or curved configuration shown in FIG. **1**). Artisans will recognize from the disclosure herein that combinations of different deployed configurations may also be used.

The anchors **104** are superelastic such that applying sufficient stress places the anchors **104** into an introduction configuration and releasing the stress allows the anchors **104** to resume their respective deployed configurations. In certain embodiments, the anchors **104** lay flat against the plurality of segments **102** in the introduction configuration during insertion of the ring **100** through the catheter. As discussed below, in other embodiments, the anchors **104** are retracted inside the segmented ring **100** in the introduction configuration during insertion of the ring **100** through the catheter. In such embodiments, the anchors **104** may be selectively deployed at a desired time (e.g., after the segmented ring **100** is properly positioned against the annulus of the heart valve). In certain embodiments, the superelastic property of the anchors **104** is used to self-propel the anchors **104** into the annulus of the heart valve.

As discussed below, the pivot **108** is used to automatically rotate the segmented annuloplasty ring **100** after it exits the catheter within the heart to align the plane of the ring **100** (in the annular operable geometry) with the plane of the heart valve. The ring **100** is pushed from the catheter in a direction that is substantially perpendicular to the plane of the heart valve (e.g., parallel to the direction of blood flow). Upon exiting the catheter, the pivot **108** rotates the ring **100** to allow the ring **100** to be properly positioned against the annulus. In one embodiment, the anchors **104** are deployed before pressing the ring **100** against the valve annulus (e.g., a balloon may be used to drive the deployed anchors into the tissue). In other embodiments, the ring **100** is pressed against the valve annulus (e.g., using a balloon) before deploying the anchors **104** and the act of deploying the anchors **104** drives the anchors **104** into the tissue. Fluoroscopy, ultrasound, and/or other imaging techniques may be used to assist in proper positioning of the ring **100** against the heart valve annulus.

The ring closure lock **106** is used to secure the two open ends of the segmented annuloplasty ring **100** to form a closed ring. As shown in FIG. **1**, in certain embodiments, the ring closure lock **106** includes a female snap **110** and a male snap **112**. As discussed below, the segmented annuloplasty ring **100** may be "snap locked" using wires or sutures to pull the male snap **112** into the female snap **110**. In certain embodiments, a gap (e.g., between about 3 mm and 5 mm) is left between the female snap **110** and the male snap **112** after the anchors **104** are deployed within the tissue of the valve annulus. Then, the two ends are snapped together to provide cinching of the valve annulus. This cinching is similar to a technique used by surgeons during open heart surgery (e.g., using sutures) to draw the valve annulus into a smaller or improved shape that reduces regurgitation of blood back through the valve.

Although not shown in FIG. **1**, certain ring embodiments include a selectively adjustable member (discussed below) for changing the size and/or shape of the segmented annuloplasty ring **100** postoperatively to compensate for changes in the size of the heart and/or the treated heart valve. Also not shown in FIG. **1**, certain ring embodiments include a cover disposed about the entire circumference of the segmented ring **100**, or selected portions thereof. For example, in certain embodiments, the cover is disposed so as to enclose the plurality of segments **102**, while leaving uncovered at least portions of the ring closure lock **106** (to permit snapping the lock together) and the pivot **108** (to allow access thereto during insertion of the ring **100**). The cover may include openings aligned with windows (discussed below) in the plurality of segments **102** through which the plurality of anchors **104** are deployed. In other embodiments, the plurality of anchors **104** are configured to puncture through the cover during deployment. The cover may include a biocompatible material such as Dacron®, woven velour, polyurethane, polytetrafluoroethylene (PTFE), heparin-coated fabric, or the like. In other embodiments, the cover includes a biological material such as bovine or equine pericardium, homograft, patient graft, or cell-seeded tissue.

FIGS. **1**A and **1**B are schematic diagrams illustrating a shape memory hypotube **113** cut to form a plurality of segments **102** for use as an outer tube (also referred to herein as an "outer hollow member") of a segmented annuloplasty ring according to one embodiment. FIG. **1**A is a plan view of a first side of the hypotube **113** in which a plurality of anchor deployment windows **114** are cut. FIG. **1**B is a plan view of a second side of the hypotube **113** that is opposite the windows **114** shown in FIG. **1**A. For illustrative purposes, FIG. **1**C is a schematic diagram illustrating a cutting pattern **116** used for laser processing the hypotube **113** shown in FIGS. **1**A and **1**B. While FIGS. **1**A and **1**B show respective (opposite) sides of the hypotube **113**, the cutting pattern **116** corresponds to the entire hypotube **113** as if the hypotube were cut along an axis **118** of the surface shown in FIG. **1**A and unrolled. Thus, for example, each window **114** shown in FIG. **1**A is shown in FIG. **1**C as being split between a first half of the window **114**(*a*) and a second half of the window **114**(*b*).

The hypotube **113** includes a through hole **120**, **121** at each end (or two perpendicular through holes at each end according to FIG. **1**C) to allow one or more pins (not shown) to couple the male and female components of the ring closure lock **106** to respective ends of the hypotube **113**. The hypotube **113** also includes a through hole **122** (the opening **122** shown in FIG. **1**A being represented in FIG. **1**C as **122**(*a*) and **122**(*b*)) for another pin (not shown) for coupling the pivot **108** to the hypotube **113**. As shown in FIG. **1**C, the hypotube **113** may also include a window **124** (passing vertically through the hypotube **113** with respect to the views shown in FIGS. **1**A and **1**B) that allows one or more lines or sutures (not shown) to exit the hypotube **113**. As discussed below, the sutures are used to snap lock the ring and/or to deploy the anchors **104**.

In FIGS. **1**A and **1**B, the hypotube **113** is shown in the elongate insertion geometry. FIG. **1**D is a schematic diagram illustrating the shape memory hypotube **113** shown in FIGS. **1**A and **1**B in an annular (D-shaped) operable geometry. In FIG. **1**D, the ring closure lock **106** and the pivot **108** are also shown. For reference, the first side shown in FIG. **1**A corresponds to the outer circumference of the ring shown in FIG. **1**D, and the second side shown in FIG. **1**B corresponds to the inner circumference of the ring shown in FIG. **1**D. FIG. **1**D shows an anterior-posterior (A-P) direction and a commissure-commissure (C-C) direction, corresponding to the anatomical structure of a human mitral-valve annulus. As discussed above, in certain embodiments, the implant size of the D-shaped hypotube **113** in the operable geometry has ratio of A-P distance to C-C distance in range between about 0.60 to about 0.70. By way of example only, and not by limitation, the table below provides some example dimensions.

Ring	Implant Shape (mm)		
Size	C-C	A-P	Ratio
28	28.00	17.36	0.62
30	30.00	18.60	0.62
32	32.22	19.84	0.62
34	34.00	21.08	0.62
36	36.00	22.32	0.62

The cutting pattern **116** shown in FIG. **1**C defines the configuration of the plurality of segments **102** and how the segments **102** interact with adjacent segments as the hypotube transitions from the elongate insertion geometry shown in FIGS. **1**A and **1**B to the annular operable geometry shown in FIG. **1**C. As shown in FIG. **1**B, the hypotube in this example embodiment includes a "tongue and groove" pattern wherein a tongue **126** of one segment interfaces with a groove **128** of an adjacent segment as the inner circumference of the ring is formed. The cutting pattern **116** provides rigidity to the hypotube **113** in the annular operable geometry, allows the hypotube **113** to easily transition from the elongate insertion geometry to the annular operable geometry, and substantially closes gaps between the segments **102** in the annular operable geometry.

In certain embodiments, deployment of the anchors **104** is accomplished using an internal anchor member that is selectively movable within the hollow tube formed by the plurality of segments **102**. For example, FIG. **2**A is a simplified schematic diagram illustrating a side view of an internal anchor ribbon **200** including the curved anchors **104** shown in FIG. **1** according to one embodiment. The curved anchors **104** may be affixed (e.g., laser welded) to the internal anchor ribbon **200** or directly cut into the internal anchor ribbon **200** (as discussed with respect to FIGS. **2**B and **2**C). Like the anchors **104**, the internal anchor ribbon **104** includes a superelastic shape memory material (e.g., Nitinol) that is heat set to the same memorized annular shape as the plurality of segments **102** (shown in FIGS. **1** and **2**A as D-shaped).

The internal anchor ribbon **200** may be slid (e.g., using wires or sutures accessible through the catheter) within the hollow tube formed by the plurality of segments **102** of the ring **100**. To reduce friction between the internal anchor ribbon **200** and the plurality of segments **102**, certain ring embodiments include an internal glide ribbon **210**. The internal glide ribbon **210** may includes a low-friction material (e.g., as a coating or covering) such as PTFE or other polymer. In addition, or in other embodiments, the internal glide ribbon **210** includes a superelastic shape memory material (e.g., Nitinol) that is heat set to the same memorized annular shape as the plurality of segments **102** (shown in FIGS. **1** and **2**A as D-shaped). Thus, certain embodiments include three D-shaped superelastic members (the outer tube of segments **102**, the internal anchor ribbon **200**, and the internal glide ribbon **210**), which cooperate to increase the rigidity of the ring **100**.

FIG. **2**B is a schematic diagram illustrating a top view of the anchors **104** cut into the internal anchor ribbon **200** shown in FIG. **2**A in the elongate insertion geometry according to one embodiment. In this example, a laser is used to cut the anchors **104** along a first side **212**, a second side **214** (e.g., in a pointed or tip shape), and a third side **216**, while leaving a fourth side **218** of the anchor **104** uncut and attached to the internal anchor ribbon **200**. After cutting, the anchors **104** are heat set to the desired memorized shape for the deployed configuration. For example, FIG. **2**C is a schematic diagram illustrating a side view of the internal anchor ribbon **200** in the elongate insertion geometry and the anchors **104** in a curled or curved deployed configuration according to one embodiment. The amount of curvature in the deployed configuration of the anchors **104** may depend on the particular application. In the example shown in FIG. **2**C, the anchors **104** fold back on themselves such that the prong or tip **220** points parallel to or away from the internal anchor ribbon **200**. FIG. **2**D is a schematic diagram illustrating a top view of the internal glide ribbon **210**, and FIG. **2**E is a schematic diagram illustrating a side view of the internal glide ribbon **210**, in the elongate insertion geometry according to one embodiment.

FIGS. **3**A and **3**B are simplified schematics illustrating cross-section side views of an annuloplasty ring **300** before (FIG. **3**A) and after (FIG. **3**B) deployment of the anchors **104** shown in FIG. **2**C according to one embodiment. For illustrative purposes, the ring **300** in FIGS. **3**A and **3**B is shown in an elongate insertion geometry. Artisans will recognize from the disclosure herein, however, that the anchors **104** are generally deployed when the ring **300** is in the annular operable geometry.

The illustrated ring **300** includes an outer tube **310** (e.g., formed by the plurality of segments **102** shown in FIG. **1**) including a plurality of anchor deployment windows **312**. During the manufacturing of the ring **300**, and before the ring **300** is loaded into the catheter, the internal anchor ribbon **200** and the internal glide ribbon **210** are inserted into the outer tube **310** in a position where the anchors **104** are prevented from exiting through the windows **312**. As shown in FIG. **3**A, inserting the internal anchor ribbon **200** into the outer tube **300** prevents the anchors from assuming their fully curved deployed configuration.

For deploying the anchors **104**, the internal anchor ribbon **200** may include (or may be attached to) a hook or loop **314** for engaging a wire or suture **316** that may be pulled by a user through the catheter (e.g., in the direction of arrow **318** in FIG. **3**A) to move the tip of each anchor **104** to a corresponding window **312**. In certain embodiments, the anchors **104** and windows **312** are arranged such that the tip of each anchor **104** reaches its respective window **312** at substantially the same time as the other anchor/window pairs. As shown in FIG. **3**B, once the tips of the anchors **104** reach the respective windows **312**, the superelasticity of the anchors **104** propels the internal anchor ribbon **200** in the opposite direction (as indicated by arrow **320**) as the anchors **104** spring out the windows **312** (as indicated by arrow **322**) to resume their curved configurations, which drives the anchors **104** into surrounding tissue (e.g., the heart valve annulus). Thus, the superelasticity of the anchors **104** allows the anchors **104** to be self-propelled into the tissue adjacent or proximate to the ring **300**.

FIG. **4**A is a schematic diagram illustrating a perspective view of a portion of the annuloplasty ring **300** shown in FIGS. **3**A and **3**B with a deployed curved anchor **104** according to one embodiment. FIG. **4**B is a schematic diagram illustrating a side view of a portion of the annuloplasty ring shown in FIG. **4**A. As shown in FIGS. **4**A and **4**B, the outer tube **310** may be cut to define segments (such as the plurality of segments **102** shown in FIG. **1**). The outer tube **310** also includes the windows **312** (one window shown in FIG. **4**A) described above and schematically represented in FIGS. **3**A and **3**B. As shown in FIG. **4**B, in certain embodiments, the deployed anchors **104** form an angle α (e.g., about 45 degrees) with a plane **410** of the ring **300** to provide the anchors **104** with improved access to the valve annulus when the ring is positioned against the valve annulus. During anchor deployment, the plane **410** of the ring **300** is substantially parallel to the plane of the valve annulus.

FIG. **5** is a simplified schematic diagram illustrating a side view of the internal glide ribbon **210** shown in FIG. **2**A used as a selectively adjustable member according to one embodiment. As discussed above, certain ring embodiments include a selectively adjustable member for changing the size and/or shape of the annuloplasty ring **100** (shown in FIG. **1**) postoperatively to compensate for changes in the size of the heart and/or the treated heart valve. Thus, FIG. **5** illustrates the internal glide ribbon **210** in the D-shaped geometry used immediately after implanting the ring, as well as an "activated" geometry or shape **210'** (shown as dashed lines) that further reduces the size of the mitral valve annulus in the (A-P) direction (as indicated by arrows **510**). Such A-P contraction improves the coaptation of the leaflets such that a gap between the leaflets sufficiently closes during left ventricular contraction. In certain embodiments, the activated shape **210'** also expands in the direction of arrows **512** (the C-C direction) to pull leaflet commissures away from each other, which draws the leaflets closer together and further improves their coaptation. However, in certain other embodiments, the ring **100** does not expand in the direction of the arrows **512**.

As used herein, "postoperatively" refers to a time after implanting an annuloplasty ring, such as the segmented annuloplasty ring **100** shown in FIG. **1** or other rings described in other embodiments, and closing the body opening through which the ring **100** was introduced into the patient's body. For example, the ring **100** may be implanted in a child whose heart grows as the child gets older. Thus, the size of the ring **100** may need to be increased. As another example, the size of an enlarged heart may start to return to its normal size after the ring **100** is implanted. Thus, the size of the ring **100** may need to be decreased postoperatively to continue to reinforce the heart valve annulus.

Thus, in certain embodiments, the ring **100** includes a selectively adjustable member (e.g., the internal glide ribbon **210** shown in FIGS. **2**A and **5**) with a shape memory material (e.g., NiTi Alloy-B) that is responsive to changes in temperature and/or exposure to a magnetic field. The ring **100** is adjusted in vivo by applying an energy source to activate the selectively adjustable member and cause it to change to a memorized shape. The energy source may include, for example, radio frequency (RF) energy, x-ray energy, microwave energy, ultrasonic energy such as focused ultrasound, high intensity focused ultrasound (HIFU) energy, light energy, electric field energy, magnetic field energy, combinations of the foregoing, or the like. For example, one embodiment of electromagnetic radiation that is useful is infrared energy having a wavelength in a range between approximately 750 nanometers and approximately 1600 nanometers. This type of infrared radiation may be produced efficiently by a solid state diode laser. In certain embodiments, the implanted ring **100** is selectively heated using short pulses of energy having an on and off period between each cycle. The energy pulses provide segmental heating that allows segmental adjustment of portions of the annuloplasty ring without adjusting the entire implant.

In certain embodiments, the ring **100** includes an energy absorbing material to increase heating efficiency and localize heating in the area of the selectively adjustable member. Thus, damage to the surrounding tissue is reduced or minimized. Energy absorbing materials for light or laser activation energy may include nanoshells, nanospheres and the like, particularly where infrared laser energy is used to energize the material. Such nanoparticles may be made from a dielectric, such as silica, coated with an ultra thin layer of a conductor, such as gold, and be selectively tuned to absorb a particular frequency of electromagnetic radiation. In certain such embodiments, the nanoparticles range in size between about 5 nanometers and about 20 nanometers and can be suspended in a suitable material or solution, such as saline solution. Coatings comprising nanotubes or nanoparticles can also be used to absorb energy from, for example, HIFU, MRI, inductive heating, or the like.

In other embodiments, thin film deposition or other coating techniques such as sputtering, reactive sputtering, metal ion implantation, physical vapor deposition, and chemical deposition can be used to cover portions or all of the selectively adjustable member. Such coatings can be either solid or microporous. When HIFU energy is used, for example, a microporous structure traps and directs the HIFU energy toward the shape memory material. The coating improves thermal conduction and heat removal. In certain embodiments, the coating also enhances radio-opacity of the annuloplasty ring implant. Coating materials can be selected from various groups of biocompatible organic or non-organic, metallic or non-metallic materials such as Titanium Nitride (TiN), Iridium Oxide (Irox), Carbon, Platinum black, Titanium Carbide (TiC) and other materials used for pacemaker electrodes or implantable pacemaker leads. Other materials discussed herein or known in the art can also be used to absorb energy.

In addition, or in other embodiments, fine conductive wires such as platinum coated copper, titanium, tantalum, stainless steel, gold, or the like, are wrapped around the selectively adjustable member (see, e.g., FIG. **10**) to allow focused and rapid heating of the selectively adjustable member while reducing undesired heating of surrounding ring **100** and/or tissues. In certain such embodiments, the electrically conductive wires are electrically insulated from other components of the ring **100**, such as the shape memory material used in the plurality of segments **102** and/or the plurality of anchors **104**.

The energy source for activating the shape memory material of the selectively adjustable member may be surgically applied after the ring **100** has been implanted by percutaneously inserting a catheter into the patient's body and applying the energy through the catheter. For example, RF energy, light energy, or thermal energy (e.g., from a heating element using resistance heating) can be transferred to the selectively adjustable member through a catheter positioned on or near the selectively adjustable member. Alternatively, thermal energy can be provided to the shape memory material by injecting a heated fluid through a catheter or circulating the heated fluid in a balloon through the catheter placed in close proximity to the selectively adjustable member. As another example, the shape memory material in the selectively adjustable member can be coated with a photodynamic absorbing material that is activated to heat the selectively adjustable member when illuminated by light from a laser diode or directed to the coating through fiber optic elements in a catheter. In certain such embodiments, the photodynamic absorbing material includes one or more drugs that are released when illuminated by the laser light. In certain embodiments, a subcutaneous electrode or coil couples energy from a dedicated activation unit. In certain such embodiments, the subcutaneous electrode provides telemetry and power transmission between the system and the annuloplasty ring. The subcutaneous electrode allows more efficient coupling of energy to the implant with minimum or reduced power loss. In certain embodiments, the subcutaneous energy is delivered to the selectively adjustable member via inductive coupling.

In other embodiments, the energy source is applied in a non-invasive manner from outside the patient's body. In certain such embodiments, the external energy source is focused to provide directional heating to the shape memory material of the selectively adjustable member so as to reduce or minimize damage to the surrounding tissue. For example, in certain embodiments, a handheld or portable device including an electrically conductive coil generates an electromagnetic field that non-invasively penetrates the patient's body and induces a current in the selectively adjustable member. The current heats the selectively adjustable member and causes the shape memory material therein to transform to a memorized shape. In certain such embodiments, the selectively adjustable member also includes an electrically conductive coil wrapped around or embedded in the memory shape material. The externally generated electromagnetic field induces a current in the selectively adjustable member's coil, causing it to heat and transfer thermal energy to the shape memory material therein.

By way of example, FIGS. **5**A, **5**B, and **5**C are schematic diagrams of circuitry for using RF induction to activate the shape memory material of the internal glide ribbon **210** according to one embodiment. FIG. **5**A illustrates circuitry located in a selectively adjustable annuloplasty ring and FIG. **5**B illustrates circuitry of an external (i.e., external to the patient) RF induction activation system according to one embodiment. FIG. **5**C is a block diagram of a system **520** for inductively activating a selectively adjustable member **522** (e.g., the internal glide ribbon **210**) of a ring according to certain embodiments.

Referring to FIGS. **5**A, **5**B, and **5**C, the RF induction activation system **520** includes a power source **524** (also referred to herein as an RF generator or RFG) capable of creating an alternating electrical signal of suitable power. The power source **524** is connected to a delivery coil **526** tuned to resonate at the same frequency as the output of the power source **524**. A capacitor **528** is used to tune the delivery coil **526** to resonate at the desired frequency. The implantable dynamically adjustable annuloplasty ring assembly includes a second (receiving) coil **530** positioned within the patient that is designed to resonate at substantially the same frequency as that of the delivery coil **526** connected to the power source **524**. A capacitor **532** is used to tune the receiving coil **530** to resonate at the desired frequency. The receiving coil **530** is connected to a heating element **534** (represented by a resistance R**1** in FIG. **5**A) wrapped around the selectively adjustable member **522** (as shown in FIG. **5**C). To activate the annuloplasty ring, the delivery coil **526** is placed near the receiving coil **530** of the selectively adjustable member **522** (e.g., near the patient's chest) and switched on. Power from the resonating magnetic field **536** (shown in FIG. **5**C) is then inductively transferred across the skin barrier to the receiving coil **530** and converted to electrical current that is subsequently used to heat the selectively adjustable member **522**. In an example embodiment, the inductance frequency is above about 100 kHz so that any leakage current that may come in contact with the patient would not cause uncomfortable sensations during activation.

In certain embodiments, embedded computing and/or remote temperature sensing is used. For example, FIG. **5**C shows that additional circuitry **538** may be implanted in the patient. The additional circuitry **538** may include transmitter circuitry (including an antenna **540**), a microprocessor, power circuitry, and temperature measuring circuitry (e.g., one or more thermocouple (TC) devices **542**, coupled to the additional circuitry **538**). Similarly, the RFG **524** may include receiver circuitry **544** (including an antenna **546**) for receiving temperature and other data from the additional circuitry **538** implanted in the patient. Although not shown, the RFG **524** may also include a processor for processing and displaying the information received from the additional circuitry **538** implanted within the patient.

The information received from the additional circuitry **538** may include, for example, the power induced in the selectively adjustable member **522**. In one embodiment, the power transferred to the selectively adjustable member **522** is measured by reading the voltage across the selectively adjustable member **522** and/or heating element **534** and, because the resistance of the selectively adjustable member **522** and/or heating element **534** is known, the power can be calculated and communicated to the RFG **524** by the telemetry link. In another example, the temperature and size of the selectively adjustable member **522** may be sensed and sent by transmitter circuitry in the additional circuitry **538** to the receiving circuitry **544** via radiotelemetry. Temperature may be sensed using the thermocouple device **542**, and the size of the ring may be deduced via built in strain gauges **548** (e.g., different resistance values equal a proportional change in size).

In one embodiment, the RFG **524** automatically finds a resonant point. The RFG **524** may be programmed to analyze wattage delivered during operation (e.g., as discussed above) and may adjust the output frequency to increase or maximize the greatest power transfer. This may be accomplished in certain embodiments by directly monitoring the current output on the delivery coil **526**, or the peak voltage induced in the receiving coil **530** via telemetry.

In one embodiment, the system **520** is capable of multiple resonant frequencies. For example, the heating element **534** (coupled to the selectively adjustable member **522**) may be electrically connected to more than one coil—each coil having a different natural resonance. In another embodiment, different coils may be attached to different heating elements or devices in the ring that can be operated separately. The transmitting power source **524** may have a set of coils (e.g., including the delivery coil **526**) that can be selectively used to couple to its respective sister coil (e.g., including the receiving coil **530**) coupled to the selectively adjustable member **522**.

By using this wireless technique of power transmission, the patient may be electrically isolated from the system **520** during activation of an implanted device. Thus, the possibility of electrocution due to a ground fault is eliminated or reduced.

In some embodiments, centering of coils is used. Such embodiments use techniques of aligning the coils, such as through the use of physical landmarks molded into a housing of the implanted receiving coil, magnets, and/or infrared lighting. For example, an infrared light emitting diode (LED) may be installed on the implanted receiving coil **530** and may light during activation. An infrared detector located on the delivery coil **526** may be configured to give a user feedback on how much light it receives. A set of magnets may also be strategically placed in the delivery coil **526** and receiving coil **530**. As the magnets are brought close together, the magnetic attraction may be utilized to align the coils **526**, **530**.

Example Ring Embodiments with Linear Anchors

FIG. **6**A is a schematic diagram illustrating a perspective view of a segmented annuloplasty ring **600** including a plurality of linear anchors **610** according to one embodiment. Seven linear anchors **610** are shown. However, artisans will understand from the disclosure herein that more linear anchors **610** or fewer linear anchors may be used. For example, certain embodiments may use ten or more linear anchors **610**.

The segmented annuloplasty ring **600** includes a plurality of segments **612** at least partially cut into a shape memory hypotube that forms a "D-shape" in the annular operable geometry (e.g., when implanted around the annulus) and may be straightened into an elongate insertion geometry for implanting the ring **600** within a patient's heart through a catheter. As discussed above with respect to FIG. **1**, the ring **600** may also include a ring closure lock **614** (shown in a connected or locked position) for snap locking the two ends of the ring together, and a pivot **616**. In the example embodiment shown in FIG. **6**A, the ring closure lock **614** is connected directly to the pivot **616** along the straight portion of the D-shaped ring.

As discussed above with respect to other embodiments, the ring **600** includes a plurality of anchor deployment windows **618** cut into the shape memory hypotube. The plurality of linear anchors **610** may be selectively deployed through the windows **618** in a manner similar to that described above for curved anchors **104**.

FIG. **6**B is a schematic diagram illustrating a side view of a portion of the annuloplasty ring shown in FIG. **6**A. As shown in FIG. **6**B, in certain embodiments, the deployed linear anchors **610** form an angle β (e.g., about 45 degrees) with a plane **620** of the ring **600** to provide the linear anchors **610** with improved access to the valve annulus when the ring is positioned against the valve annulus. During anchor deployment, the plane **620** of the ring **600** is substantially parallel to the plane of the valve annulus. As shown in FIG. **6**B, the linear anchors **610** may include a pointed prong **621** for penetrating tissue and a barb **622** that secures the anchor to the tissue.

FIG. **7** is a simplified schematic diagram illustrating a side view of an internal anchor member **700** including linear anchors **710** according to one embodiment. The linear anchors **710** may be affixed (e.g., laser welded) to the internal anchor member **700**. In the embodiment shown in FIG. **7**, however, the internal anchor member **700** and linear anchors **710** are cut from a single superelastic shape memory (e.g., Nitinol) hypotube. FIG. **7**, for example, shows remaining tubular portions **712** after the hypotube is cut to form prongs **714** of the linear anchors **710**. The remaining tubular portions **712** facilitate sliding (e.g., using wires or sutures accessible through the catheter) the internal anchor member **700** coaxially within the hollow tube of the ring (e.g., within the segmented annuloplasty ring **600** shown in FIG. **6**).

The internal anchor member **700** is heat set to the same memorized annular shape as the ring. The anchors prongs **714** can be heat set to protrude outward through windows cut in the segmented annuloplasty ring **600**. Barbs **716** may be laser welded to the prongs **714** to form the linear anchors **710**. The linear anchors **710** are retracted/deployed by sliding the internal anchor member **700** within the segmented annuloplasty ring **600**.

FIG. **8**A is a schematic diagram illustrating an enlarged perspective view of a single-barbed anchor **808** of a percutaneous transcatheter annuloplasty ring **800** in an affixation configuration according to one embodiment. The anchor **808** includes a prong **810** and a single barb **812** welded to the prong **810**. The prong **810** is integrated with or connected to an inner tube member (not shown, but see FIG. **7**) and protrudes through a window **820** cut in an outer tube member formed by a plurality of segments **802**.

FIG. **8**B is a schematic diagram of an enlarged perspective view of a dual-barbed anchor **858** of a percutaneous transcatheter annuloplasty ring in an affixation configuration according to one embodiment. The anchor **858** includes a prong **860** and two barbs **862** welded to the prong **860**. The prong **860** is integrated with or connected to an inner tube member (not shown) and protrudes through a window **820** cut in an outer tube member formed by a plurality of segments **852**.

FIG. **9** is a simplified schematic diagram illustrating a side view of the internal anchor member **700** shown in FIG. **7** and a selectively adjustable member **900** according to one embodiment. As discussed above, the selectively adjustable member **900** is configured to change the size and/or shape of the annuloplasty ring **600** postoperatively to compensate for changes in the size of the heart and/or the treated heart valve. In FIG. **9**, the selectively adjustable member **900** is shown passing through the remaining tubular portions **712** of the cut hypotube of the internal anchor member **700**. In such embodiments, the selectively adjustable member **900** may be rod shaped and may have an outer diameter of about 40 microns. In other embodiments, the selectively adjustable member **900** may be located adjacent to the internal anchor member **700** (e.g., around the external circumference, the internal circumference, or lateral to the internal anchor member **700**).

The selectively adjustable member **900** includes a shape memory material (e.g., NiTi Alloy-B) that is responsive to changes in temperature and/or exposure to a magnetic field. The selectively adjustable member **900** may be activated, for example, using any of the energy sources or methods described above with respect to FIGS. **5**, **5**A, **5**B, and **5**C. The activated geometry of the selectively adjustable member **900**, according to certain embodiments, reduces the size of the mitral valve annulus in the AP direction.

FIG. **10** is a schematic diagram illustrating a partial cross-sectional view of the selectively adjustable member **900** shown in FIG. **9** according to one embodiment. The selectively adjustable member **900** in this example includes a shape memory rod **1010**, a heating element **1012** (e.g., electrically conductive wire) coiled around the shape memory rod **1010**, and an electrically insulating cover **1013** surrounding the shape memory rod **1010** and heating element **1012**. The electrically insulating cover **1013** prevents current passing through the heating element **1012** from flowing to nearby metals or other shape memory alloys in the ring (e.g., the outer segmented annuloplasty ring **600** and/or the internal anchor member **700**), or to surrounding tissue. The electrically insulating cover **1013** may also provide thermal insulation to protect the surrounding tissue from excessive heat.

As shown in FIG. **10**, the selectively adjustable member **900** may include leads **1014**, **1016** for providing induced current through the heating element **1012**. The leads **1014**, **1016** may exit through the septal wall, the right atrium subclavian vein, or both leads may follow the ring contour and exit at P_1/P_2 leaflet junction or P_3/P_2 leaflet junction.

In certain embodiments, the receiving coil **530** (shown in FIGS. **5**A and **5**C) and any associated internal circuitry may be placed anywhere within the patient and outside the heart of the patient. For example, the receiving coil **530** and/or additional circuitry **538** may be implanted immediately below the surface of the skin and coupled to the heating element **1012** (coupled to the selectively adjustable member **900**) via one or more wires extending into the heart. In another embodiment, the receiving coil **530** and associated internal circuitry may be integrated with the annuloplasty ring and/or the selectively adjustable member **900**. For example, the receiving coil **530** and additional circuitry **538** may be incorporated internal to the annuloplasty ring. In still another embodiment, the receiving coil **530** may be implanted adjacent the lead wire and/or the receiving coil, in close proximity to the selectively adjustable member **900**.

Example Deployment Embodiments

As discussed above, the annuloplasty ring embodiments disclosed herein are configured for percutaneous transcatheter delivery and fixation to heart valves. The rings may be delivered through a catheter to the mitral valve, for example, using a trans-septal approach, a retrograde approach, or a trans-apical approach. For example, FIG. **11**A is a schematic diagram illustrating a trans-septal approach for endovascular delivery of an annuloplasty ring (not shown) to the mitral valve **1110** of a heart **1100** according to one embodiment. For illustrative purposes, a partial cross-section of the heart **1100** is illustrated to show the right atrium RA, right ventricle RV, left atrium LA, and left ventricle LV. For clarity, certain features (e.g., papillary muscles and chordae tendineae) are not shown. In the trans-septal approach shown in FIG. **11**A, the left atrium LA is approached by advancement of a catheter **1112** through the inferior vena cava **1114**, into the right atrium RA, across the interatrial septum **1116**, and into the left atrium LA. The annuloplasty ring may then be delivered through the catheter **1112** into the atrium and anchored to the annulus of the mitral valve **1110**.

As shown in FIG. **11**A, the catheter **1112** is delivered percutaneously into the heart **1100**. A guiding sheath (not shown) may be placed in the vasculature system of the patient and used to guide the catheter **1112** and its distal end **1118** to a desired deployment site. In some embodiments, a guide wire (not shown) is used to gain access through the superior or inferior vena cava **1114**, for example, through groin access for delivery through the inferior vena cava **1114**. The guiding sheath may be advanced over the guide wire and into the inferior vena cava **1114** shown in FIG. **11**A. The catheter **1112** may be passed through the right atrium RA and towards the interatrial septum **1116**. Once the distal end **1118** of the catheter **1112** is positioned proximate to the interatrial septum **1116**, a needle or piercing member (not shown) is advanced through the catheter **1112** and used to puncture the fossa ovalis or other portion of the interatrial septum **1116**. In some embodiments, the catheter **1112** is dimensioned and sized to pass through the fossa ovalis without requiring a puncturing device. That is, the catheter **1112** may pass through the natural anatomical structure of the fossa ovalis into the left atrium LA.

Similarly, any chamber (LV, RV, LA, RA) of the heart **1100** may be approached through the inferior vena cava **1114**. For example, the right ventricle RV may be approached through the inferior vena cava **1114**, into the right atrium RA, and through the tricuspid valve **1120**. A variety of other endovascular approaches may also be used.

FIG. **11**B is a schematic diagram illustrating an example retrograde approach of an annuloplasty ring (not shown) to the mitral valve **1110** of a heart **1100** according to another embodiment. In FIG. **11**B, a femoral approach is shown wherein the delivery catheter **1112** is advanced through the aorta **1122** and the aortic valve **1124**. Typically, the catheter **1112** is advanced through a sheath positioned within the femoral artery (not shown). Under fluoroscopy or other methods of guidance, the distal end of the catheter **1112** is guided within the left ventricle LV and turned (e.g., as shown with a "U-turn" **1126**) within the left ventricle LV so as to pass through the leaflets of the mitral valve **1110** and into the left atrium LA. After verification of the appropriate positioning of the catheter **1112**, a guide wire (not shown) may be inserted through the catheter **1112** into the left atrium LA, which may then be used to guide one or more other catheters into the left atrium LA for delivering and anchoring the annuloplasty ring to the annulus of the mitral valve **1110**.

FIG. **11**C is a schematic diagram illustrating an example trans-apical approach of an annuloplasty ring (not shown) to the mitral valve **1110** of a heart **1100** according to another embodiment. In this example, the catheter **1112** is shown passing through the apex **1130** of the heart **1100**, through the left ventricle LV, through the leaflets of the mitral valve **1110**, and into the left atrium. The annuloplasty ring, may be delivered through the catheter **1112** into the left atrium LA and anchored to the annulus of the mitral valve **1110**. In one embodiment, a needle or trocar may be used to puncture through the apex **1130** to create a small opening through which a guide wire (not shown) can be inserted through the left ventricle LV into the left atrium LA. Then, the guide wire may be used to guide successively larger and stiffer catheters so as to gradually increase the size of the opening in the apex **1130** of the heart **1100**.

FIGS. **12**A and **12**B are schematic diagrams illustrating a delivery system **1200** for implanting a segmented annuloplasty ring **1202** within a heart according to certain embodiments. FIG. **12**A illustrates a perspective view of the delivery system **1200**, including a distal end **1210** and a proximal end **1212**. FIG. **12**B illustrates an enlarged view of the proximal end **1212** shown in FIG. **12**A. The distal end **1210** is discussed below in more detail with respect to FIGS. **13**A and **13**B. The delivery system **1200** includes an outer jacket delivery catheter **1214** having a proximal end attached to a hemostatic connector **1216**.

The proximal end **1212** of the system **1200** includes a first torque controller **1218** for controlling a first suture **1219** used for snapping together the ends of the ring **1202**, a second torque controller **1220** for controlling a second suture **1221** for deploying anchors (not shown) from the ring **1202**, and a third torque controller **1222** for controlling a ring deployment wire **1223** for orienting the ring **1202** within the heart and releasing the ring **1202** from the delivery system **1200**. The first suture **1219** and/or the second suture **1221** may include a resilient material capable of providing a pulling force to elements within the ring **1202**, as discussed below. Thus, the first suture **1219** and/or the second suture **1221** may include, for example, Teflon, steel, or Nitinol. In one embodiment, the ring deployment wire **1223** includes a superelastic shape memory material (e.g., Nitinol) for orienting the ring **1202**, as discussed below. In some embodiments, the first suture **1219**, the second suture **1221**, and/or the ring deployment wire **1223** are Teflon-coated.

The first torque controller **1218**, the second torque controller **1220**, and the third torque controller **1222** are connected to the hemostatic connector **1216** through a four-port connector **1217**. In one embodiment, the four-port connector **1217** comprises a luer port. The first torque controller **1218** is connected to the four-port connector **1217** through a spring tension luer **1225**, a spring tension assembly **1226** and a spring tension plunger **1228**. The spring tension assembly **1226** includes an internal spring (not shown) against which the plunger **1228** is biased to provide a desired amount of tension to the first suture **1219** under the control of the torque controller **1218**, and to pull the first suture **1219** to snap-lock the ends of the ring **1202** together. Similarly, the second torque controller **1220** is connected to the four-port connector **1217** through a spring tension luer **1230**, a spring tension assembly **1232** and a spring tension plunger **1234** to provide a desired amount of tension to the second suture **1221** under the control of the second torque controller **1220**, and to pull the second suture **1221** to deploy the anchors. In one embodiment, the first suture **1219** and/or the second suture **1221** may include a notch (not shown) within or near the ring **1202** that is configured to break the respective suture **1219**, **1221** by applying additional tension after the suture **1219**, **1221** has performed its respective function (e.g., after the suture **1219** snaps the ends of the ring **1202** together or after the suture **1221** deploys the anchors). The third torque controller **1222** is connected to the four-port connector **1217** through an adapter **1224**, such as a Touhy borst adapter.

FIGS. **13**A, **13**B, **13**C, **13**D, **13**E, **13**F, and **13**G are schematic diagrams illustrating the front of the delivery system **1200** shown in FIG. **12**A according to certain embodiments. FIG. **13**A illustrates a perspective view of the distal end **1210** of the delivery system **1200** up to the hemostatic connector **1216** of the proximal end. FIG. **13**B illustrates an enlarged view of a portion of the distal end **1210** shown in FIG. **13**A. The distal end **1210** includes a catheter shaft **1314** sized and configured to pass through the outer jacket delivery catheter **1214**, a ring shuttle **1316** configured to be removably coupled to the pivot **108** of the segmented annuloplasty ring **1202**, a first deployment lumen **1320** through which the first suture **1219** passes for snapping together the ends of the ring closure lock **106**, a second deployment lumen **1324** through which the second suture **1221** passes for deploying anchors (not shown) as discussed above, and a third deployment lumen **1328** (FIG. **13**C) through which the ring deployment wire **1223** passes for orienting the ring **1202** within the heart and releasing the ring **1202** from the ring shuttle **1316**.

FIGS. **13**A and **13**B show a first side of the distal end of the ring shuttle **1316** including the first deployment lumen **1320** (for snap locking the ring **1202**) and the second deployment lumen **1324** (for deploying anchors), with the ring **1202** in the annular operable geometry having its plane perpendicular to the longitudinal axis of the outer jacket delivery catheter **1214** and the catheter shaft **1314** (e.g., as it would be oriented inside the heart and aligned with the valve annulus). In FIG. **13**C, a second side of the distal end of the ring shuttle **1316** is shown including the third deployment lumen **1328**, with the ring **1202** in the elongate insertion geometry aligned with the longitudinal axis of the catheter shaft **1314** and ready to be loaded into the outer jacket delivery catheter shown in FIGS. **13**A and **13**B. In the configuration shown in FIG. **13**C, the distal end of the ring deployment wire **1223** includes a bend or hook **1332** as it passes through a hole in the pivot **108**. The ring deployment wire **1223** includes a superelastic shape memory material (e.g., Nitinol). As discussed below, bending the distal end of the ring deployment wire **1223** into the hook **1332** shape spring loads the ring **1202** within the outer jacket delivery catheter **1214** such that the ring **1202** automatically rotates about the pivot **108** upon exiting the outer jacket delivery catheter **1214**.

FIG. **13**D is a perspective view of the ring **1202** partially deployed from the distal end **1210** of the outer jacket delivery catheter **1214** in a first deployment stage. In the first stage, the ring **1202** is still substantially in the elongate insertion geometry. As shown in FIG. **13**D, the first suture **1219** for snapping together the ends of the ring **1202** passes through the male snap **112** of the ring closure lock **106**.

FIG. **13**E is a perspective view of the ring **1202** in a second stage of partial deployment from the outer jacket delivery catheter **1214**. In the second stage, the portion of the ring **1202** that has exited the outer jacket delivery catheter **1214** has begun to transition (due to the shape memory materials used in the ring **1202**) from the elongate insertion geometry to the annular operable geometry. The ring **1202** may include a window (not shown), e.g., laser cut through the outer hypotube along with the plurality of segments, that allows the first suture **1219** to exit the ring **1202**.

FIG. **13**F is a perspective view of the ring **1202** in a third stage of deployment in which the ring shuttle **1316** has substantially pushed the ring **1202** out of the outer jacket delivery catheter **1214**, but the plane of the ring **1202** is still aligned with (e.g., approximately parallel to) the longitudinal axis of the outer jacket delivery catheter **1214**. This example shows the configuration immediately before the ring deployment wire **1223** cooperates with the pivot **108** to rotate the ring **1202** (see FIG. **13**G). At this stage, the hook **1332** shape in the superelastic ring deployment wire **1223** is ready to unload (return to its straight configuration) as soon as the outer jacket delivery catheter **1214** no longer prevents it from doing so.

FIG. **13**G is a perspective view of the ring **1202** in a fourth stage of deployment in which the plane of the ring **1202** (in its annular operable geometry) has been changed to be perpendicular to the longitudinal axis of the outer jacket delivery catheter **1214**. As shown in FIG. **13**G, the superelastic ring deployment wire **1223** has returned to its heat set (memorized) straight configuration. At this stage, the axis of the ring **1202** is parallel to the plane of the heart valve annulus.

In further stages of deployment, the ring **1202** may be pressed against (e.g., using a balloon) the heart valve annulus before deploying the anchors (such as the curved anchors **104** shown in FIGS. **4**A and **4**B) by pulling the second suture **1221** toward the proximal end of the second deployment lumen **1324**. As discussed above, certain anchor embodiments propel themselves into the tissue of the heart valve annulus upon being deployed. In other embodiments, the anchors (such as the linear anchors **710** shown in FIG. **7**) may be deployed before pressing the ring **1202** against the annulus. After the ring **1202** is anchored to the heart valve annulus (or after a balloon is holding the ring against the annulus), the ring deployment wire **1223** may be pulled from the hole in the pivot **108** to release the ring **1202** from the ring shuttle **1316**. The first suture **1219** and the second suture **1221** may also be cut and/or pulled from the ring **1202** before the catheters **1214**, **1314** are removed from the heart.

FIGS. **14**A, **14**B, **14**C, **14**D, **14**E, **14**F, and **14**G are schematic diagrams illustrating perspective, partially cross-section views of a heart **1100** during the introduction and affixation of a segmented annuloplasty ring **1400** to the annulus of the mitral valve **1110** according to certain embodiments. As shown, an outer jacket delivery catheter **1410** extends from the left ventricle into the left atrium through the leaflets of the mitral valve **1110**. Thus, this illustrated embodiment may correspond to, for example, a trans-apical approach or a retrograde approach, as discussed above. Artisans will recognize from the disclosure herein, however, that similar principles as those illustrated may be used for trans-septal approaches.

In FIG. **14**A, the ring **1400** is in an elongate insertion geometry as it is pushed into the left atrium from a distal end of the catheter tube **1410**. As discussed herein, a wire or suture **1412** used for snapping together the ends of the ring **1400** is shown extending from a first end of the ring **1410**. FIG. **14**B shows the ring **1400** partially deployed from the catheter **1410**. As discussed above, the superelastic shape memory components of the ring **1400** cause the exposed end of the ring **1400** to return to its annular shape (D-shape) as it exits the catheter **1410**.

FIG. **14**C illustrates the ring **1400** fully deployed from the catheter **1410** and transitioned from the elongate insertion geometry to the D-shape operable geometry. In this embodiment, the suture **1412** (shown in FIGS. **14**A and **14**B) has been pulled so as to snap together the two ends of the ring **1400**. In other embodiments, however, the ends of the ring **1400** are not snapped together until the ring **1400** has been anchored in place to the valve annulus. See, for example, FIGS. **16**B and **17**.

For illustrative purposes, the plane of the ring **1400** in FIG. **14**C is shown as parallel to the longitudinal axis of the catheter **1410** and an inner catheter shaft **1414**. In this position, the plane of the ring **1400** may be considered as perpendicular or substantially perpendicular to the valve annulus. In other words, the plane of the ring **1400** as shown in FIG. **14**C is substantially perpendicular to the direction of blood flow through the mitral valve **1110**. As discussed above, the inner catheter shaft **1414** (e.g., via a ring shuttle) is coupled to and cooperates with the **1416** to automatically rotate the ring **1400** as it exits the outer catheter **1410** so that the plane of the ring **1400** is parallel to the plane of the valve annulus, as shown in FIG. **14**D. In other words, in FIG. **14**D, the plane of the ring **1400** is substantially parallel to the blood flow through the mitral valve **1110**. In FIG. **14**D, a ring deployment wire **1413** is shown, such as the ring deployment wire **1223** discussed above. For clarity, the ring deployment wire **1413** is not shown in FIG. **14**C.

FIG. **14**E illustrates the ring **1400** positioned on or next to the annulus of the valve **1110** with the anchors **1418** deployed. At this stage, in this embodiment, the anchors **1418** are either not embedded within the annulus tissue or are only partially inserted within the annulus tissue. In other embodiments, however, the anchors **1418** self-propel themselves into the annulus tissue when deployed. See, e.g., FIGS. **16**B and **17**. FIG. **14**E shows a balloon catheter **1420** extending through the distal end of the outer catheter **1410**.

FIG. **14**F shows a balloon **1422** of the balloon catheter **1420** in the process of being inflated and driving the anchors **1418** into the annulus tissue around the valve **1110**. FIG. **14**G graphically illustrates the anchors **1418** embedded within the tissue **1424** (see FIG. **14**G) of the valve annulus. In FIG. **14**G, the catheters have been removed and the ring **1400** is securely attached to the annulus of the mitral valve **1110** to restore the valve opening to its approximate original size and operating efficiency.

The balloon shown in FIG. **14**F includes two sections and may be considered a “multi-chamber” balloon with two chambers. In other embodiments, a balloon with a single chamber or a balloon with more than two chambers may be used to position the ring **1400** against the valve annulus and/or to drive the anchors **1418** into the surrounding tissue. In the embodiment shown in FIG. **14**F, the inflated balloon **1422** may reduce or prevent the flow of blood through the mitral valve during at least part of the implantation procedure. In such embodiments, inflation of the balloon **1422** may last 20 seconds or less to prevent adverse consequences of occluding the mitral valve. In other embodiments, blood is allowed to flow through the mitral valve during the entire procedure. For example, FIG. **15** is a schematic diagram illustrating a perspective, partially cross-section view of the heart **1100** during the introduction and affixation of the segmented annuloplasty ring **1400** using an expandable cage or basket **1500**, instead of the balloon shown in FIG. **14**F, according to one embodiment. The basket **1500** includes a plurality of flexible members **1510** that lay flat against a central rod **1514** during insertion of the basket **1500** through the catheter **1410** (shown in FIG. **14**A) and may be forced into an expanded configuration (shown in FIG. **15**) when the central rod **1514** is pushed into an end cap **1512**. In another embodiment, the plurality of flexible members **1510** comprise a superelastic material so as to spring from the catheter **1410** into the expanded configuration shown in FIG. **15**.

FIG. **16**A is a flowchart of a method **1600** for repairing a defective heart valve according to one embodiment. The method **1600** includes percutaneously introducing **1610** a distal end of a first catheter into a left atrium of a heart and inserting **1612** a segmented annuloplasty ring, attached to a second catheter, through the first catheter into the left atrium. The ring includes a superelastic shape memory material that transforms the ring from an elongate insertion geometry to an annular operable geometry as the ring exits the distal end of the first catheter. The method **1600** further includes automatically rotating **1614** the ring to change a plane of the ring from a first direction that is parallel to the second catheter to a second direction that is parallel to a plane of the mitral valve annulus, and pulling **1616** a first suture, connected to the ring through the second catheter, to couple the ends of the ring together. The method **1600** includes pulling **1618** a second suture, connected to the ring through the second catheter, to deploy a plurality of tissue anchors from the ring. Then, inserting **1620** an expansion device through the first catheter into the left atrium and activating the expansion device to press the ring against the valve annulus and drive the anchors into the surrounding tissue. The method **1600** further includes detaching **1622** the ring from the second catheter and the first and second sutures, and remove the first and second catheters from the heart.

FIG. **16**B is a flowchart of a method **1630** for repairing a defective heart valve according to another embodiment. The method **1630** includes percutaneously introducing **1632** a distal end of a first catheter into a left atrium of a heart, and inserting **1634** a segmented annuloplasty ring, attached to a second catheter, through the first catheter into the left atrium. The ring includes superelastic shape memory material that transforms the ring from an elongate insertion geometry to an annular operable geometry as the ring exits the distal end of the first catheter. The method **1630** further includes automatically rotating **1636** the ring to change a plane of the ring from a first direction that is parallel to the second catheter to a second direction that is parallel to a plane of the mitral valve annulus, and inserting **1638** an expansion device through the first catheter into the left atrium and activating the expansion device to press the ring against the valve annulus. Pressing the ring against the annulus at this stage allows the subsequent deployment of the anchors to propel the anchors into the annulus tissue. Thus, the method **1630** further includes pulling **1640** a first suture, connected to the ring through the second catheter, to deploy a plurality of tissue anchors from the ring. Each of the plurality of anchors includes a superelastic shape memory material that propels the superelastic anchors into the tissue of the valve annulus. The method **1630** further includes pulling **1642** a second suture, connected to the ring through the second catheter, to couple the ends of the ring together and cinch the valve annulus to a desired size. The method **1630** also includes detaching **1644** the ring from the second catheter and the first and second sutures, and removing the first and second catheters from the heart.

FIG. **17** is a schematic diagram illustrating a perspective, partially cross-section view of the heart **1100** during the introduction and affixation of a segmented annuloplasty ring **1700** according to another embodiment. In this embodiment, a balloon **1710** is inflated before anchors **1712** are deployed. The balloon **1710** in this embodiment is "donut-shaped" (i.e., it includes a central opening) to allow blood to flow through the valve during the entire procedure. With the ring **1700** pressed against the valve annulus, the anchors **1712** are deployed. As discussed above, the anchors **1712** comprises a superelastic shape memory material that assists in driving the anchors **1712** into valve annulus tissue **1713**. For illustrative purposes, the anchors **1712** in FIG. **17** are shown with dashed lines to represent being embedded within the tissue **1713**.

Additional Example Embodiments

FIG. **18** is a schematic diagram of a percutaneous transcatheter annuloplasty ring **1800** in an annular operable geometry according to one embodiment. The annuloplasty ring **1800** can be affixed to heart tissue in and/or around a defective heart valve to treat (e.g., reduce) regurgitation of blood through leaflets of the heart valve. For example, the annuloplasty ring **1800**, in the operable geometry, may be affixed to the annulus of the heart valve and used to cinch the annulus to draw the opening smaller or into an improved shape that reduces regurgitation of blood back through the valve. FIG. **19**A is a schematic diagram illustrating the percutaneous transcatheter annuloplasty ring **1800** of FIG. **18** in an insertion geometry according to one embodiment. FIG. **19**B is a schematic diagram of the percutaneous transcatheter annuloplasty ring **1800** transitioning from the insertion geometry shown in FIG. **19**A to the operable geometry shown in FIG. **18** according to one embodiment.

Referring generally and collectively to FIGS. **18**, **19**A, and **19**B, the annuloplasty ring **1800** may include a plurality of segments **1802** flexibly coupled together. Flexible coupling of the plurality of segments **1802** may be accomplished with a plurality of hinges **1804**. The annuloplasty ring **1800** may further include a securement mechanism **1806**, such as a pin or clasp, to couple together ends of the annuloplasty ring **1800** to form the annular operable geometry. In the displayed example, the hinges **1804** comprise pin joints and the securement mechanisms **1806** comprise pins. The plurality of segments **1802** and plurality of hinges **1804** allow the annuloplasty ring **1800** to unfold or open from a curved and/or annular operable geometry into an elongate flexible insertion geometry as illustrated in FIG. **19**A.

The plurality of segments **1802** may be arranged in a serial or linear arrangement (e.g., a chain of interconnected segments **1802**) having a first end **1920** and a second end **1922**. The plurality of segments **1802** may be formed of a biocompatible material, or a combination of multiple biocompatible materials, including but not limited to Nitinol and plastic. The plurality of segments **1802** may be formed to enhance flexibility when in the insertion geometry and to enhance rigidity when in the operable geometry. The plurality of segments **1802** and/or the annuloplasty ring **1800** may include shape memory material to bias or otherwise aid in transitioning the annuloplasty ring **1800** to the curved operable geometry.

The plurality of hinges **1804** couple together the plurality of segments **1802**. Each segment **1802** may be coupled to an adjoining segment via a corresponding hinge **1804**. The hinges **1804** may be configured to facilitate folding or closing the annuloplasty ring **1800** to transition between the insertion geometry and the operable geometry, as shown in FIG. **19**B. In certain embodiments, each of the plurality of hinges **1804** is configured to lock into a secured state when the associated (adjoining) segments **1802** are in the operable geometry. Thus, a hinge **1804** may allow adjoining segments **1802** to freely rotate within a range of motion to provide flexibility, and the hinge **1804** may lock to limit rotation of the adjoining segments **1802** and provide rigidity when rotation of the adjoining segments exceeds the range of motion and the adjoining segments **1802** are in their respective positions of the operable geometry. In another embodiment, the plurality of hinges **1804** may include a flexible piece of material. For example, a hinge **1804** may be formed of a portion of the same material as the plurality of segments **1802**. In still another embodiment, the plurality of hinges **1804** are integrated with, or formed integrally with, the plurality of segments **1802**. For example, the plurality of segments **1802** and the plurality of hinges **1804** may be cut from a single piece of material, such as a Nitinol tube.

A ring closure lock **1910** secures the first end **1920** to the second end **1922** to form the circular or annular shape of the operable geometry. The ring closure lock **1910** of the illustrated embodiment is a snap-lock in which a ball **1912** (male snap) on the second end **1922** is received and snaps into a mating socket **1914** (female snap) on the first end **1920** when the ball **1912** is urged toward and into the socket **1914** with sufficient force. In another embodiment, the ring closure lock **1910** may include a clasp or other locking mechanism. In another embodiment, the ring closure lock **1910** may be any locking mechanism that allows a first component to easily slide past a second component in a first direction but that prevents the first component from sliding back in the opposite direction past the second component. In another embodiment, the ring closure lock **1910** may include magnets configured to attract the ends **1920**, **1922** together.

A ring closing mechanism **1916**, such as a suture or wire, may be mounted across the ends **1920**, **1922** to facilitate bringing the ends **1920**, **1922** of the annular ring **1800** together and engagement of the ring closure lock **1910**. In the illustrated embodiment, the ring closing mechanism **1916** may be a suture. The suture **1916** may be configured and arranged through an eyelet **1932** or hook (or around a knob) on the second end **1922**. The ends of the suture **1916** may also be threaded through an eyelet **1930** on the first end **1920** and back through the catheter out of the patient's body. The ends of the suture **1916** may be pulled or otherwise manipulated by a practitioner from external to the patient's body to draw the second end **1922** toward the first end **1920**. In this manner, the ball **1912** can be forced into the socket **1914** to secure the ends **1920**, **1922** together and the annuloplasty ring **1800** in the operable geometry. Once the ring lock closure is secured (e.g., locked) in place, one end of the suture **1916** can be pulled to pull the suture **1916** through the eyelets **1930**, **1932** and out of the patient's body.

The operable geometry of the annuloplasty ring **1800** may be curved to align or substantially conform to the sized and/or shape of an annulus of a properly functioning heart valve of the type to be repaired. In the illustrated embodiment, the operable geometry is circular or annular, as shown in FIG. **18**. The operable geometry may be designed and configured to provide structure and rigidity to properly cinch and/or support a defective valve to correct regurgitation of blood back through the valve. In one embodiment, the operable geometry provides rigidity in at least a direction transverse to a plane of the curved shape of the operable geometry. The plane of the curved shape may be defined by a longest diameter of the curved shape and a second diameter of the curved shape that is perpendicular to the first diameter. Stated differently, the operable geometry may provide rigidity along (e.g., in a direction parallel to) a circumferential axis of the curved shape. The circumferential axis may be defined through the center of the opening of the ring and extending parallel to a direction of a flow of blood through the annuloplasty ring **1800** when it is properly implanted in the heart valve. In FIG. **18**, the circumferential axis may be defined by a line extending from the center of the annuloplasty ring **1800** directly out of and perpendicular to the page. The annuloplasty ring **1800** in the operable geometry may, in one embodiment, be rigid radially relative to the circumferential axis. In another embodiment, the operable geometry may be flexible radially relative to the circumferential axis.

The insertion geometry, as shown in FIG. **19**A, allows the annuloplasty ring **1800** to be flexible and in an elongate and somewhat linear state to be inserted into a catheter tube. An annuloplasty ring, such as annuloplasty ring **1800**, disposed in a catheter tube can be delivered and affixed to the defective heart valve via a percutaneous transcatheter delivery method. More specifically, a tip of a catheter tube of a delivery apparatus can be percutaneously inserted into a vascular structure of a vasculature of a body of a patient. The catheter tube of the delivery apparatus can be guided through the vasculature of the patient into a chamber of a heart of the patient and adjacent to the defective heart valve to be repaired. For example, delivery of the annuloplasty ring to the mitral valve may be accomplished via retrograde approach from the femoral artery, or an antegrade approach via a trans-septal entry. As another example, delivery of the annuloplasty ring into the tricuspid valve may be accomplished via an approach from the inferior or superior vena cava.

The annuloplasty ring **1800** may be configured to enable cinching of the heart tissue proximate the valve and/or cinching of the annulus of the valve, after affixation of the annuloplasty ring **1800** (e.g., postoperatively), to reduce regurgitation of blood back through leaflets of the valve.

FIG. **20**A is a schematic diagram illustrating a percutaneous transcatheter annuloplasty ring **2000** according to another embodiment. The annuloplasty ring **2000** is shown in FIG. **20**A in an annular operable geometry with anchors **2008** in an introduction configuration. FIG. **20**B is a schematic diagram illustrating an enlarged side view of the annuloplasty **2000** ring of FIG. **20**A. The annuloplasty ring **2000** may include an inner support structure **2040** and an outer shell **2042**. In FIG. **20**A, the inner support structure **2040** is shown in phantom lines as being hidden by the outer shell **2042**. The inner support structure **2040** may be formed of a plurality of segments **2002**, as shown in FIG. **1**D and discussed more fully in other embodiments disclosed herein. The outer shell **2042** may be formed of a thin super-elastic material, such as Nitinol. The anchors **2008** may extend from and/or be integrated with the outer shell **2042**. Super-elastic shape memory material in the plurality of segments **2002** of the inner support structure **2040** and/or the outer shell **2042** enable the annuloplasty ring **2000** to transition between an insertion geometry and an operable geometry.

The anchors **2008**, when in an introduction configuration, may be folded or wrapped to lie in close proximity to the outer shell **2042**, as shown in FIG. **20**B, so as to not protrude away from the surface of the annuloplasty ring **2000**. The anchors **2008** may include a prong **2052** and a barb **2054** at an end of the prong. The barb **2054** may facilitate securement of the anchor **2008** in tissue.

FIG. **20**C is a schematic diagram of the annuloplasty ring **2000** of FIG. **20**A with the anchors **2008** in an affixation configuration protruding away from the annuloplasty ring **2000**. An integrated diaphragm **2062** may be integrated with the outer shell **2042** and/or the inner support structure **2040**. Inflation of the integrated diaphragm **2062** unfurls the anchors **2008** to expose the barbs **2054** for affixation (implantation) of the annuloplasty ring **2000** into a heart valve annulus. In another embodiment, rather than including an integrated diaphragm **2062**, a balloon catheter (not shown) may be used to deploy the anchors **2008**.

Those having skill in the art will understand from the disclosure herein that many changes may be made to the details of the above-described embodiments without departing from the underlying principles of the invention. The scope of the present invention should, therefore, be determined only by the following claims.

The invention claimed is:

1. A method for percutaneous transcatheter repair of a mitral valve in a heart, the method comprising: percutaneously introducing a distal end of a first catheter into a left atrium of the heart;

inserting a segmented annuloplasty ring, attached to a second catheter, through the first catheter into the left atrium, the ring including a superelastic shape memory material that transforms the ring from an elongate insertion geometry to an annular operable geometry as the ring exits the distal end of the first catheter;

automatically rotating the ring to change a plane of the ring from a first direction that is parallel to the second catheter to a second direction that is parallel to a plane of a mitral valve annulus;

pulling a first suture, connected to the ring through the second catheter, to couple the ends of the ring together;

pulling a second suture, connected to the ring through the second catheter, to deploy a plurality of tissue anchors from the ring; and

inserting an expansion device through the first catheter into the left atrium and activating the expansion device to press the ring against an annulus of the mitral valve so as to drive the anchors into surrounding tissue.

2. The method of claim **1**, further comprising:

detaching the ring from the second catheter and the first and second sutures; and

removing the first and second catheters from the heart.

3. The method of claim **1**, wherein percutaneously introducing the distal end of the first catheter into the left atrium of the heart comprises a trans-septal approach through the inferior vena cava, right atrium, and interatrial septum into the left atrium.

4. The method of claim **1**, wherein percutaneously introducing the distal end of the first catheter into the left atrium of the heart comprises a retrograde approach through the aorta, aortic valve, left ventricle, and mitral valve into the left atrium.

5. The method of claim **1**, wherein percutaneously introducing the distal end of the first catheter into the left atrium of the heart comprises a trans-apical approach through the apex of the heart, left ventricle, and mitral valve into the left atrium.

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